

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
Products Liability Litigation)
)
) Phoenix, Arizona
) March 2, 2018
)
)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

FINAL PRETRIAL CONFERENCE

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10:01:31 1 P R O C E E D I N G S

2

3 THE COURTROOM DEPUTY: MDL 2015-2641, in the matter
4 of Bard IVC Filters Product Liability, on for a final pretrial
10:01:05 5 conference.

6

Will the parties please announce.

7

8 MS. REED ZAIC: Julia Reed Zaic on behalf of

plaintiff steering committee.

9

MR. O'CONNOR: Mark O'Connor, co-lead for plaintiffs.

10:01:17 10

MR. LOPEZ: Ramon Lopez on behalf of the plaintiffs.

11

THE COURT: Morning.

12

MR. LOPEZ: Morning, Your Honor.

13

MR. NORTH: Good morning, Your Honor.

14

Richard North, James Condo, Elizabeth Helm,
10:01:26 15 Brandee Kowalzyk, Taylor Daly, Amanda Sheridan, and
16 Matthew Lerner on behalf of the defendants.

17

THE COURT: Okay. Good morning.

18

All right. Counsel, what I'd like to do today is
19 first go through juror issues, hear if you have objections to
any of the hardship excusals I've made, and then hear
20 challenges for cause based on the questionnaires, if there
21 are clear grounds for those challenges.

23

Then we'll talk a little bit more about the process
24 for jury selection. And I then have identified, oh, probably
10:02:14 25 20 issues that we need to touch on from reviewing the final

10:02:18 1 pretrial order that I want to talk to you about. Then
2 there's a few others. In fact, I just thought of one. Let
3 me remember what it is.

4 It's gone.

10:02:37 5 Then I'll be happy to hear whatever issues you want
6 to raise.

7 So as you saw in my order of the 23rd, I identified,
8 I think, 77 jurors that I thought should be excused for
9 hardship, and then yesterday we sent out an e-mail with two
10 additional jurors, 79 and 161. Their questionnaires came in
11 late. I thought they should also be excused for hardship.

12 So what I'd like to know now is whether you disagree
13 with my conclusion that those persons should be excused, and
14 if so we can talk about it. And on any that you don't
15 disagree on or that I conclude should still be excused for
16 hardship, we're going to exclude them and they won't be
17 invited in on March 14th for jury selection.

18 So let's start with plaintiffs. Do you have any
19 hardship excusals you disagree with?

20 MR. LOPEZ: No, Your Honor.

21 THE COURT: All right. How about defendants?

22 MR. NORTH: None for the defendants, Your Honor.

23 THE COURT: Okay. Then what we will do is exclude
24 all of the jurors that were identified in the February 23rd
10:03:48 25 order, that's at Docket 10240, as well as Jurors 79 and 161.

10:04:03 1 (The Court and the judicial assistant confer.)

2 THE COURT: Let me read something here.

3 All right. What Nancy just called to my attention
4 is that Juror 191, who we had not excused for hardship, sent
10:04:54 5 us an e-mail yesterday, and he indicated that there have been
6 some lumps found in one of his eyes and they've scheduled eye
7 surgery for March 29th to address those. So it seems to me
8 we should excuse Juror 191 as well.

9 Any objection to that?

10:05:17 10 MR. LOPEZ: No, Your Honor.

11 MR. NORTH: No objection, Your Honor.

12 THE COURT: Okay.

13 Okay. Let's talk about challenges for cause that
14 you've identified. The idea here, obviously, is to identify
10:05:56 15 individuals who really don't require any further follow-up
16 questioning. It's clear from what they've said in their
17 questionnaire that they should be excused for cause. If
18 they're arguable, I think my conclusion is going to be that
19 we need to bring them in and ask them follow-up questions.
20 But we don't need to spend time on that if there's some folks
21 that clearly should be excused on the basis of their
22 questionnaire answers.

23 So why don't we start with plaintiffs' counsel.

24 MR. LOPEZ: Well, in truth, Your Honor, we're not
10:06:30 25 prepared to do that, but we can be. I mean, the individual

10:06:32 1 that's involved with that -- I didn't know we were going to
2 address that today.

3 THE COURT: My order said we would do that today.

4 MR. LOPEZ: I -- you know, I -- we will be ready to
10:06:41 5 do that today. Can we not do it right now? Is that something
6 we can do later so we can make sure that the person on our
7 team that's addressing that can be available, at least by
8 phone?

9 THE COURT: Has that person reviewed all of these
10:06:56 10 juror questionnaires?

11 MR. LOPEZ: Absolutely.

12 THE COURT: And when can that person be available?

13 MR. LOPEZ: Sometime this morning.

14 THE COURT: Well, can you find out, just so that we
10:07:03 15 can figure out when we can do that today?

16 MR. LOPEZ: Yes, Your Honor.

17 THE COURT: What do you need to do? Call them or
18 something?

19 MR. LOPEZ: Yes.

10:07:10 20 THE COURT: Do you want to do that now?

21 MR. LOPEZ: Sure. Should I step out and do that?

22 THE COURT: Yeah.

23 Defense counsel, are you ready to do that?

24 MR. NORTH: Yes, your Honor, we are prepared.

10:07:20 25 THE COURT: We'll find out when plaintiff's counsel

10:07:22 1 can do it.

2 I assume, Mr. Lopez, that that person you will want
3 to have listening in when we talk about defense's challenges
4 for cause?

10:07:33 5 MR. LOPEZ: Yes, Your Honor.

6 THE COURT: Okay. All right. We'll find out when
7 that can be done when counsel comes back into the courtroom.

8 With respect to the other jury selection issues, as
9 you know, I indicated in a previous order that we were going
10 to seat nine jurors. We only need six for a civil jury, but
11 that would allow us to lose three potentially to cold or flu
12 or something like that and still have enough to deliberate.

13 And, as you know, all who remain at the end of the
14 trial will deliberate. There are no alternates.

10:08:10 15 With each side having three peremptory strikes, that
16 means we need 15 jurors at the end of the challenges for
17 cause to pick a jury. I'm guessing there will be some jurors
18 who show up on the 14th who will also tell us they have a
19 hardship. It's happened every time we've done this, despite
10:08:34 20 the fact they may have said no in their questionnaire. So we
21 may lose a few more to that because it's a long trial.

22 With the need to find 15, and recognizing we'll lose
23 a few for hardship, my inclination would be to bring in about
24 50 jurors. I think that would give us enough to deal with
10:08:54 25 any challenges for cause that arise. But I'm interested in

10:08:58 1 your thoughts, whether you think that's too many, too few.

2 We could lose 35 jurors to challenges for cause or hardship
3 and still have enough to pick the jury.

4 MR. LOPEZ: I don't know. That's tripled. I mean,
10:09:14 5 that's three times. That's pretty good, Judge. I mean, three
6 times the final venire. Yeah.

7 MR. NORTH: I think that sounds about correct,
8 Your Honor.

9 THE COURT: Traci, what do you think?

10:09:31 10 (The Court and the courtroom deputy confer.)

11 THE COURT: I think we'll do 60. Traci's made the
12 good point that we'd rather have too many than too few, and
13 you never know what kind of issues might come up, including
14 some no-shows on the morning. So we'll ask 60 jurors to come
10:10:25 15 in.

16 One of the things you need to do in the next few
17 days is put together your witness list in a form that we can
18 have the jury office hand it to the jurors when they show up
19 on the morning of the 14th. I don't want to stand here and
10:10:45 20 read it to them. What I'd much rather do is have them look
21 it over while they're assembling in the jury room, and then
22 when they come up we'll ask if they know any of those
23 witnesses. So if you work together, get together the
24 complete list, I would suggest you do it in a way where it
10:11:04 25 leaves some space between each name so if the jurors want to

10:11:07 1 make a note or something, they can do that. And get that to
2 Nancy, if you would, in a Word form. That way we'll finalize
3 that and have that ready to hand out to the jury on the 14th.
4 So when they come up here, they will have had a chance to
10:11:20 5 look over that list.

6 We've also handed to you today, I think, Nancy
7 handed you the proposed preliminary instructions and voir
8 dire.

9 There's not much in the voir dire. It's just to
10:11:34 10 make sure they don't know anybody they've seen in the
11 courtroom, read them the witness list, ask if they know
12 anybody else on the jury panel, and just a couple of
13 follow-up questions.

14 Look over that, if you would, today at some point,
10:11:47 15 and before we break remind me we need to come back to that so
16 that we add anything else you think needs to be in that voir
17 dire.

18 On the preliminary instructions, they're basically
19 what you all proposed, but look over those as well. I took
10:12:04 20 out two of the instructions you recommended, which one was on
21 the preponderance of the evidence burden of proof, and the
22 other was on clear and convincing burden of proof. It seems
23 to me out of context that doesn't mean anything to the jury.
24 We need to be able to tell them as to a specific claim what
10:12:19 25 the burden of proof is. So I pulled those out. I just don't

10:12:23 1 think that adds much. If you disagree, I'm happy to hear
2 your thoughts.

3 I put into the second preliminary instruction the
4 summary of the case from the questionnaire. If you think we
10:12:39 5 need to do more than that, by all means let me know. If you
6 think, for example, that we should give them something of a
7 preview of the nature of the claims and the things that need
8 to be proved, that's the place to do it. So think about
9 whether that's necessary as opposed to just describing the
10:12:57 10 case for them.

11 And before we finish today, we'll come back and talk
12 about the voir dire and the preliminary instructions.

13 The -- so what we'll do, we'll seat all of the
14 jurors in order by number here in the courtroom. We'll put
10:13:25 15 16 of them in the box, and then starting over on my left at
16 17, we'll line them up behind you. And I'll ask my voir dire
17 questions of them. Then you can ask follow-up questions
18 based on the questionnaires.

19 But they ought to be a follow-up, a juror-specific
20 follow-up. In other words, you have something you want to
21 follow up from an answer they gave. What you shouldn't do in
22 your questioning is launch into some new subject and ask it
23 of the entire panel. The point of the questionnaire was to
24 cover that ground.

25 And if it is a sensitive question, I will tell the

10:14:03 1 jurors ahead of time that if they'd rather answer in a less
2 public way, they can just say that in response and we'll take
3 that answer after we've excused the rest of the panel.

4 So after you've asked your follow-up questions --
10:14:15 5 and I'll probably have you come and stand on my side of the
6 lectern so you can face them and pull the mic over as you ask
7 those questions. After you've asked those follow-up
8 questions, we'll excuse the panel. I'll hear any challenges
9 for cause. We'll then identify the 15 lowest numbered jurors
10 that remain, and you'll exercise your peremptory strikes.
11 And, as you know, under the rules, those are simultaneous and
12 secret, so you each just identify the three you want struck,
13 and that will give us our nine. If you have overlap in your
14 strikes, we'll just take the nine lowest numbered for the
10:14:52 15 jury.

16 The rest of my jury trial practices are pretty
17 standard.

18 I allow the jurors to take notes. They'll have
19 notebooks. I instruct them not to deliberate until the end
10:15:04 20 of the case. I don't have jurors ask questions of witnesses.

21 I think that sort of covers what I wanted to say
22 about jury selection.

23 Do you all have questions?

24 MR. O'CONNOR: Your Honor, yes.

10:15:29 25 THE COURT: Pull the mic over, would you please,

10:15:30 1 Mr. O'Connor.

2 MR. O'CONNOR: Pardon me?

3 THE COURT: Pull the mic over.

4 MR. O'CONNOR: Thank you. Yes, sir.

10:15:35 5 Your Honor, when you gave --

6 THE COURT: Hold on. Hold on just a minute,

7 Mr. O'Connor.

8 Traci tells me somebody in the courtroom has your
9 cell phone on, even if it's on mute. You've got to turn it
10 off. It's interfering with the sound system because it's --

11 MS. REED ZAIC: Possibly could have been mine because
12 I jumped out for a minute.

13 THE COURT: Okay.

14 All right. Go ahead, Mr. O'Connor.

10:15:54 15 MR. LOPEZ: Airplane mode is not good enough?

16 THE COURT: Airplane mode works. It just can't
17 receive messages or it interferes with our sound system.

18 What were you going to say, Mr. O'Connor?

19 MR. O'CONNOR: Just we wanted to raise an issue about
20 voir dire, Your Honor. In CMO 28, the Court had indicated the
21 parties would submit voir dire questions, and then, after the
22 questionnaire, you advised that there would be follow-up
23 questions. The problem we have is that we would like to
24 submit some additional questions that pertain to the FDA. The
25 questionnaire didn't really cover that, and we think that

10:16:31 1 there should be some questions directed to the panel that deal
2 with issues that weren't completely covered or couldn't have
3 been covered in the questionnaire.

4 I'm trying to count how many times it was
10:16:43 5 referenced, but I think it really was just does anybody have
6 anybody or know anybody that works with FDA.

7 THE COURT: Give me an example.

8 MR. O'CONNOR: Of a question for the FDA?

9 THE COURT: Yeah, the kind of question you want to
10:16:55 10 ask.

11 MR. O'CONNOR: Well, first question is what
12 experience or feelings you have about the FDA --

13 THE COURT: I'm not going to ask open-ended questions
14 like that because I don't want to take a half hour and listen
10:17:06 15 to 50 different jurors respond. What I want to do is ask
16 questions that go to the issue of whether it would affect
17 their fairness and impartiality, in which event they raise
18 their hand and we can then follow up.

19 MR. O'CONNOR: Could we submit some proposed
10:17:18 20 questions with that criteria to you for your review?

21 THE COURT: Yeah. Talk to defense counsel. See if
22 you can agree. If you can't, I'll be happy to look at them.
23 But I don't want them to be questions that call for a
24 narrative of everybody on the panel because we're going to be
10:17:32 25 pressed for time, and if we do that it's going to take us an

10:17:35 1 extra couple hours to pick the jury.

2 MR. O'CONNOR: All right. Then we will talk to
3 opposing counsel and submit our proposed questions with what
4 you just outlined.

10:17:44 5 THE COURT: Yeah. And why don't you e-mail them to
6 our office. You can file them, as well, if you want them on
7 the record, but e-mail them so we take note of them, and Nancy
8 will get them to me and I'll look at them.

9 MR. O'CONNOR: When would you like those by?

10:18:00 10 THE COURT: Middle of next week is fine.

11 MR. O'CONNOR: All right. Thank you.

12 THE COURT: Are there any other questions on jury
13 selection?

14 MR. NORTH: Your Honor, this is probably a silly
15 question on my part, but I want to be clear. Once we finish
16 with challenges for cause today, will you just take the first
17 60 jurors, call those in beginning with number 1 --

18 THE COURT: Yes.

19 MR. NORTH: -- that are still available?

20 THE COURT: Yes. That's what we'll do. And what we
21 do is we put it on a recording or a website, I can't remember
22 which, that the jurors check, and those are the people called
23 in. So yeah, it's going to be the 60 lowest numbered that
24 remain after today.

25 MR. NORTH: Okay. Thank you, Your Honor.

10:18:34 1 THE COURT: Anything else?

2 MR. NORTH: No.

3 THE COURT: What did you find out?

4 MS. REED ZAIC: He's going to call in.

10:18:41 5 Excuse me, Your Honor. He's going to call in. I
6 think there was the issue of the static. I'm seeing e-mails
7 pouring in about that. So I don't know if that is fixed.
8 But I know my associate can't understand what is going on
9 right now.

10:18:57 10 THE COURTROOM DEPUTY: I had it muted before.

11 THE COURT: We muted it because there's static on the
12 conference line. I don't think that's from a phone. I think
13 that's the conference line. It sounds differently than what
14 we hear.

10:19:16 15 Who is it that is going to call in?

16 MS. REED ZAIC: David Wenner, Your Honor.

17 (The Court and the courtroom deputy confer.)

18 THE COURT: Well, we've got this static problem on
19 the phone line.

10:20:03 20 MR. LOPEZ: We have one of these WiFi. We just
21 turned it off and it didn't change.

22 THE COURT: Yeah, it's not in the courtroom. This
23 sound we're hearing is a problem with the conference line.
24 And so it's going to be hard for him to participate with that.
25 He's not in town, I take it?

10:20:21 1 MS. REED ZAIC: No.

2 MR. LOPEZ: No. I think -- I know he's not.

3 THE COURT: Well, I think what we should do is this:
4 We're going to mute that line again. You're getting e-mails
10:20:34 5 from folks saying they can't hear what we're saying because of
6 the static?

7 Somebody in the back is nodding.

8 I don't know what to do on that, because I think
9 that's the conference call line. I don't think there's
10:20:45 10 anything we can do about that.

11 So what we're going to do on the jury challenge for
12 cause issue, I think, is hold that for a moment. We're going
13 to talk through other issues. If those issues take us to the
14 noon hour, then we're going to take a break anyway, and maybe
10:21:02 15 when they call back in we'll have a static-free line and we
16 can do the jury challenges for cause at that time.

17 MS. REED ZAIC: And we'll have it resolved on our
18 end, Your Honor.

19 THE COURT: Okay.

20 10:21:12 All right. Anything else, then, on jury selection
21 from anybody?

22 MS. REED ZAIC: I have one clarification, Your Honor.
23 You said you don't allow questions of witnesses, but the
24 jurors are able to ask the Court questions for clarification?

25 10:21:24 THE COURT: Well, they certainly can during

10:21:27 1 deliberations.

2 MS. REED ZAIC: During deliberations only, but not
3 during trial?

4 THE COURT: Right. Well, I mean, they can if a
10:21:32 5 problem comes up. You know, I've had jurors send notes
6 saying, We can't see the exhibits or We can't hear counsel.
7 But I don't tell them that they can ask questions about the
8 case as the case is going on. In our state court, jurors are
9 allowed to ask questions of witnesses. They go through the
10:21:48 10 judge. But we don't follow that practice here. So that's
11 what I meant to address.

12 Mr. North, did you have another question?

13 MR. NORTH: No. Nothing further, Your Honor.

14 THE COURT: Okay. We'll come back to the challenges
10:21:59 15 for cause, then.

16 What I want to do now is turn to the final pretrial
17 order and a number of issues that I noticed as we went, as I
18 went through it.

19 You have included some stipulations on pages 4 and 5
10:22:26 20 of the final pretrial order. Would you like me to read those
21 to the jury? Would you like to present them to the jury in
22 some manner? Is it stuff that will be covered otherwise so
23 that it doesn't need to be shared with the jury? What are
24 your thoughts?

10:22:51 25 What I've done in other cases where parties want

10:22:53 1 stipulated facts shared with the jury, is I've read them to
2 the jury before opening statements. I've told them that
3 those facts are established.

4 MR. LOPEZ: You are talking about Section C.

10:23:06 5 THE COURT: C(1).

6 MR. LOPEZ: Just (1)?

7 THE COURT: C(1)(a) through (k) are your stipulations
8 of facts.

9 MR. LOPEZ: I mean, usually when we stipulate to
10 facts, it is something the jury probably should -- I have no
11 problem you reading those to the jury, Your Honor.

12 MR. NORTH: Yes, Your Honor, I think that would be
13 the way to do it.

14 THE COURT: Okay. Then what I will do is I will read
15 those stipulations just before opening statements and tell
16 them that the parties have agreed on those facts.

17 All right. Let me go through some other issues that
18 some of you -- that you raised in the final pretrial order.

19 On page 13, the issue was raised as to whether
20 Dr. Amer, A-M-E-R, can be included as a nonparty at fault.

21 That was resolved in the order that I issued yesterday.

22 On page 14, lines 2 through 4, plaintiffs contend
23 that the assumption of the risk doctrine is not applicable to
24 the facts, circumstances, and claims in this case. And it's
25 not mentioned again in the final pretrial order, that I could

10:25:05 1 see. No discussion or argument about it. So I didn't know
2 what plaintiffs' counsel want me to do with that issue, if
3 anything, other than perhaps that's what you're going to
4 argue.

10:25:18 5 MR. LOPEZ: I didn't hear the last thing you said,
6 Your Honor. The last part you said, I couldn't hear.

7 THE COURT: I don't know what you want me to do with
8 that issue. There's no briefing, there's no discussion, it
9 wasn't in a motion in limine.

10:25:33 10 MR. LOPEZ: I think on that issue, we just wait and
11 see how the evidence develops, Your Honor. If we want to
12 offer a jury instruction with respect to that issue and once
13 we know what the rest of the jury instructions are going to
14 be, we can wait.

10:25:49 15 THE COURT: All right. Then there's no ruling needed
16 on that issue now.

17 All right. On page 14, as well, down in paragraph
18 (k), is the issue of whether intervening cause can be argued.
19 That was resolved in yesterday's ruling also.

10:26:18 20 On page 23, in paragraph D, plaintiffs question
21 whether defendants can offer evidence at trial of the lack of
22 FDA enforcement related to the G2 filter. That was addressed
23 somewhat in the ruling, but not -- it wasn't squarely raised
24 in any motion in limine, although it was addressed,
10:26:51 25 obviously, in some of the other motions.

10:26:53 1 This is plaintiffs' issue. Is there anything more
2 that you seek to assert with respect to that issue,
3 Mr. Lopez?

4 MR. LOPEZ: Yes, Your Honor. I think we need some
10:27:06 5 clarification, frankly, about the extent to which the defense
6 is going to be able to even talk about that in opening
7 statement. I've got some examples. And whatever the Court's
8 ruling is, we'll adjust to it. But I was drawing your
9 attention to page 18 of the motion, the order that you served
10 yesterday. I think it falls under -- most of this that you're
11 going to try to enter comes into 801, evidence goes to 801,
12 where silence can be a statement for purposes of hearsay rules
13 where the person intended it as an assertion.

14 I mean, that's -- I'm just going to -- may I
10:27:47 15 approach?

16 THE COURT: Yeah, that's fine.

17 MR. LOPEZ: I'll give you some examples. This is
18 Mr. North's opening statement in the *Phillips* case. And I
19 just need to know whether or not this is the type of evidence
10:28:10 20 that is going to be allowed in our case.

21 Number one is, "Well, you will see that Bard did, in
22 fact, conduct thorough and rigorous testing of the device."
23 That part's fine. "That Bard was completely open and
24 transparent with the FDA and that Bard acted appropriately
10:28:28 25 regarding the filter." That's number one.

10:28:30 1 I want to read all of them.

2 "The fact remains that in every test performed in
3 the development of the filter, it passed the test, and those
4 tests results were given to the FDA."

10:28:43 5 Number three, "Bard was open and transparent with
6 the FDA."

7 "You'll see the evidence that the FDA looked closely
8 at all of our submissions and sent lengthy sets of questions
9 back to Bard saying, Please tell us this, please explain how
10 you came up with this, what's the parameters of this. You'll
11 see all of that dialogue back and forth as the agency
12 investigated."

13 The -- number seven, "The clinical trial, you'll see
14 that Bard gave all the results, the good and the bad, to the
15 company. But what was concerning to the FDA was to see what
16 the rate was. You know, are Bard filters dangerous because
17 they're migrating or causing death much more than competitive
18 filters?"

19 Next. "The agency was given every single report of
20 complication that we had. We told the FDA, you know, we're
21 already working on the second generation, and one of the
22 things we're trying to do based on the clinical performance
23 of our first retrievable filter is make the second generation
24 filter more resistant to migration. We're also trying to
25 improve its performance on other parameters."

10:29:54 1 Next. "And the FDA knew that was in the works. In
2 fact, you'll see evidence that in March of 2005, after most
3 of these deaths associated with the filter had been reported,
4 Bard met with the FDA and an entire list of doctors and
10:30:09 5 scientists and specialists with the FDA to discuss both their
6 performance data on the Recovery filter, the complication
7 rates, and the development of the new G2 filter."

8 Next. "Bard didn't hide anything. It gave the
9 agency the data, warts and all."

10:30:24 10 We don't have any evidence, Your Honor, about what
11 really happened at FDA and what FDA's position is about all
12 of this, or who at FDA or if FDA really did any of this. We
13 just have the hearsay evidence in this case that they're
14 going to say that FDA had everything and they didn't take any
10:30:44 15 action, and therefore, by their inaction, they must have
16 approved the manner in which we were conducting ourselves
17 with respect to these products.

18 I mean, that's the kind of evidence that, frankly,
19 is not fair to the plaintiff, because we're not allowed to do
10:31:00 20 discovery on the other party that was involved in this
21 process.

22 THE COURT: What is your objection to any of those
23 statements you just read?

24 MR. LOPEZ: My objections to them is that they are
10:31:10 25 rank hearsay.

10:31:11 1 THE COURT: How is it hearsay for Mr. North to say
2 what Bard gave the FDA?

3 MR. LOPEZ: They can do that. They can do that.

4 THE COURT: That's all I heard.

10:31:19 5 MR. LOPEZ: What you heard was that the FDA -- well,
6 here --

7 THE COURT: I didn't hear any statements about what
8 the FDA thought or did in what you just read.

9 MR. LOPEZ: So how do we -- well, let's do this: How
10 do we know whether or not the agency was given every single
11 report of complication that we had? I mean, how do we know
12 that?

13 THE COURT: You mean Bard saying that?

14 MR. LOPEZ: Yeah.

10:31:41 15 THE COURT: They put a witness on and they testify
16 about that.

17 MR. LOPEZ: Okay. Then how do we counter that?

18 THE COURT: You cross-examine. You're saying they
19 can't present evidence of what they did? On hearsay grounds?

10:31:51 20 MR. LOPEZ: No. They can say what they did, but --

21 THE COURT: So if they say "We gave every report we
22 had to the FDA" --

23 MR. LOPEZ: Right.

24 THE COURT: -- how is that hearsay?

10:31:59 25 MR. LOPEZ: Well, I mean, what's the relevance of

10:32:00 1 that?

2 THE COURT: Well, it's relevance to the overall FDA
3 issue. But you seem to be arguing it's hearsay.

4 MR. LOPEZ: Well, I mean -- but I guess my point is
10:32:09 5 what is the relevance of them giving it to the FDA? What does
6 that do with respect to whether or not Bard did what it was
7 supposed to do under Georgia law to conduct appropriate
8 testing to warn and to design this thing appropriately? The
9 fact that they gave something to FDA? Who? I mean, the FDA
10 is -- it's like there -- there's not like this receiving line
11 of scientists. They just sent it somewhere. What does that
12 mean? The jury -- it's completely misleading to the jury.

13 THE COURT: It sounds like --

14 MR. LOPEZ: They say they sent something to the
10:32:42 15 FDA --

16 THE COURT: It sounds like you are -- and tell me if
17 I'm wrong about this, but you're arguing the point you made in
18 the *Cisson* motion, that they should not be able to present to
19 the jury their -- well, the 510(k) process, what they gave the
10:32:56 20 FDA, what clearance they received.

21 MR. LOPEZ: If we see -- if they have evidence and we
22 have the document and we can see the document that they say
23 they sent to FDA, that's fine. But for them to stand up and
24 say We gave every single report of complications to the FDA --

10:33:15 25 THE COURT: Let's assume for a minute -- I'm

10:33:16 1 assuming, Mr. Lopez -- that if Mr. North makes that statement,
2 he's going to have a witness to back it up. If he doesn't,
3 the jury will be instructed that what lawyers argue are not
4 facts. On both sides. But let's assume, to follow along in
10:33:29 5 your point, that some Bard witness gets on the stand and says,
6 I was in charge of communicating with the FDA and we gave the
7 FDA every study that we had.

8 What is your -- the basis for an objection to that
9 testimony?

10 MR. LOPEZ: What is every study and where did it go?
11 Who looked at it? What did FDA do with it?

12 THE COURT: What is the evidentiary basis for that
13 objection?

14 MR. LOPEZ: The evidentiary basis for it? It's
10:33:56 15 probably a 403 objection, to start with, because it misleads.
16 It pretends like that was an event that FDA received, that
17 somebody at FDA looked at, and that FDA had some meeting with
18 a committee and either did something or didn't do something.
19 The fact that you sent something to FDA could be a big vast
10:34:19 20 black hole where it went nowhere.

21 THE COURT: It sounds like you're arguing -- and tell
22 me if I'm wrong about this -- that it shouldn't be admitted
23 because you don't think it's true.

24 MR. LOPEZ: Well, that -- I mean, that's certainly
10:34:32 25 one of the -- I mean, if we could prove it's not true because

10:34:36 1 we're able to find somebody at FDA that we could depose or
2 come and testify, we could deal with the truth or the nontruth
3 if we had an opportunity to do that. We don't have an
4 opportunity in dealing with the FDA to do that because we
10:34:49 5 cannot depose FDA. They can say we sent seven of these tests
6 to FDA, not have any document that shows it was submitted, and
7 I have to sit there and say, Okay. I can't do anything about
8 that because I can't subpoena somebody at FDA and say, By the
9 way, did Bard really send those, all of the tests that they
10:35:09 10 had to, that they claim they did? I can't do it.

11 They're just -- the assumption is going to be,
12 number one, it happened, and number two is that when it got
13 to FDA there was a big scramble of a bunch of scientists that
14 sat around and analyzed it and didn't do anything about it,
10:35:22 15 and therefore the product must be okay, no issue. That's
16 what the intent of this is in saying, We sent stuff to FDA.

17 When you look at the record of the communications
18 with FDA, it's -- sometimes it's not even an M.D. or Ph.D.
19 Sometimes it's an RN. So they get to say we sent it to FDA,
10:35:44 20 when, in fact, they sent it to somebody who -- we don't know
21 what they did with it.

22 THE COURT: Why isn't everything you just said not an
23 appropriate jury argument?

24 MR. LOPEZ: Well, then -- okay. Then we get to the
10:35:57 25 point where -- you know, it's interesting because I have the

10:35:59 1 papers that they filed in another case where they file for
2 *Buckman*. And I'll just read some of the language -- this
3 is -- this was good rationale when they're trying to keep
4 *Buckman* out, but it's not for purposes of keeping the stuff
10:36:14 5 that we want to get in or the things they want to get in and
6 how we want to combat it.

7 In their *Buckman* argument they say it's
8 second-guessing what FDA would have done had it received the
9 information that was allegedly withheld from it by the
10:36:37 10 defendant company. They used that to say you can't talk
11 about that. To show that Bard misled the FDA and what the
12 FDA would have done had it not been misled is inadmissible.

13 Evidence or testimony that, in this case *Bayer*,
14 failed to adequately or timely provide information to the FDA
10:36:58 15 pursuant to FDA reporting obligations that run to the FDA
16 generally irrelevant to the plaintiffs' state law claims, and
17 thus inadmissible.

18 THE COURT: I disagree with those arguments.

19 MR. LOPEZ: Then the next one. "Bard will likely
10:37:13 20 offer evidence" -- this is Bard's statement in their brief.
21 "Bard will likely offer evidence of its submission to and
22 interactions with the FDA as evidence of industry standards
23 and how Bard met FDA's requirements. This evidence is based
24 on a manufacturer's duty to disclose to the FDA, not a duty
10:37:30 25 that is owed to the plaintiff or their prescribing

10:37:32 1 physicians."

2 I mean, that's what we're faced with when they're
3 able to put on this kind of evidence. Because I guess
4 what -- I guess -- the main point is this, Judge: Is this
10:37:46 5 jury now supposed to sit in judgment of whether the FDA did
6 its job or whether the FDA should have done something or
7 shouldn't have done something? They're not going to be
8 charged with that obligation, with the duty to make that
9 decision.

10:38:02 10 THE COURT: Well, Mr. Lopez, when we started on this
11 issue, it was based on your assertion in the final pretrial
12 order that defendants cannot offer evidence of a lack of FDA
13 enforcement.

14 MR. LOPEZ: True.

10:38:17 15 THE COURT: You haven't talked about that yet.
16 Everything you've talked about so far is what Bard can say
17 about what they gave the FDA.

18 MR. LOPEZ: Well, Your Honor, the purpose of them
19 doing that is because the FDA didn't do anything. They kept
10:38:30 20 letting them redesign and redesign and keep the product on the
21 market until we now have their seventh generation on the
22 market. It took them 12 years to send out a warning letter to
23 them that they didn't go through a 510(k) process for their
24 Recovery call. That thing did not go -- the FDA knew that.
10:38:47 25 Somebody at FDA. I don't know who it was. I don't know

10:38:50 1 whether it was a nurse, Ph.D, or MPH, knew that there wasn't a
2 510(k) with the Recovery Cone when it was submitted in 2002.
3 13 years later we get a warning letter. The FDA finally wakes
4 up and says no 510(k) on the warning letter.

10:39:08 5 We have years of misreporting of adverse events that
6 are revealed in that warning letter.

7 Bard went back and did a two-year retrospective, if
8 you'll recall, and they found that almost 300 of them were
9 either misreported, they weren't categorized right, and they
10 didn't report 44. But that was true in 2007 and 2008, when
11 FDA got those reports. So now in 2015 they wake up and say,
12 By the way, you didn't report these appropriately. They want
13 the jury to believe that these were all reported
14 appropriately, that when it gets to FDA, FDA looks at them,
15 takes no action, and therefore FDA's absolutely blessed
16 everything they've done.

17 THE COURT: Based on all you've just said, what
18 exactly are you suggesting I should keep out of evidence?

19 MR. LOPEZ: Well, let's put it this way: The mere
20 fact that they sent something -- I'd like to know what the
21 relevance is that they reported something to FDA.

22 THE COURT: Tell me exactly what you think I should
23 keep out of evidence.

24 MR. LOPEZ: Well, I mean, just their rank statements
25 that we gave all that stuff to FDA. I want to see what it is

10:40:32 1 they claim to they gave to FDA, and I want proof by some
2 submission that they did it. I don't want to hear about some
3 meeting they went to that I wasn't at, that I can't
4 cross-examine the other people that were at, where they had
10:40:44 5 this great conversation with all these scientists and they
6 brought all their people and yet at the end of the meeting we
7 all said -- the FDA patted them on the back and said, You're
8 doing a great job. Go back, we approve, we condone everything
9 you're doing. I don't want to hear about that because it's
10:41:02 10 not fair.

11 THE COURT: The point isn't what you want to hear
12 about. The point is what I can exclude on the basis of rules
13 of evidence.

14 MR. LOPEZ: Okay. Well, if I say I don't want to
10:41:09 15 hear about, it means I would ask you to exclude it, Judge.

16 THE COURT: I understand that, but I can't exclude it
17 because you don't want to hear about it. I've got to have an
18 evidentiary basis for excluding it. And I think one of the
19 arguments you're making is not really based on the rules of
10:41:22 20 evidence, it is an argument that it is unfair for them to tell
21 their side of the FDA communication when we can't do discovery
22 on the other side.

23 MR. LOPEZ: Right. That's one of them.

24 THE COURT: That's not a rules of evidence issue.
10:41:34 25 That's just sort of a basic fairness argument, I think.

10:41:40 1 MR. LOPEZ: It is, but I mean, I think, frankly, you
2 said it best in your order, that silence is an assertion.

3 THE COURT: But those cases don't talk about silence
4 being hearsay if it's an assertion from a party. Those cases
10:42:01 5 talk about silence being an assertion if it's an assertion by
6 the declarant.

7 MR. LOPEZ: Okay.

8 THE COURT: So if the FDA intended its silence to be
9 an assertion, then that assertion can be treated under the
10:42:16 10 hearsay rules.

11 MR. LOPEZ: I understand.

12 THE COURT: Okay. I'm not understanding --

13 MR. LOPEZ: Maybe --

14 THE COURT: -- you think the FDA's lack of action
10:42:27 15 over these years was intended by FDA to be an assertion.

16 MR. LOPEZ: Well, that's what they're going to
17 suggest to the jury. I mean, the fact that the FDA took no
18 action, the assertion is that the FDA found nothing wrong with
19 their conduct. And the issue here is not going to be about
10:42:48 20 that. Not about what they did -- in other words -- so let's
21 do this, Judge: Let's assume we have evidence, even through
22 their own witnesses, that we cross-examine them and we show
23 them a federal regulation, and they agree they have to follow
24 this federal regulation independent of FDA. For example,
10:43:06 25 let's say we asked one of their quality guys under the

10:43:10 1 following circumstances, is this device considered adulterated
2 under the federal regulations, and that person says yes.

3 Okay.

4 The next question is: If the device is adulterated,
10:43:21 5 isn't it true that you should stop selling it until you
6 unadulterate it? Right? Well, they're going to say, Well,
7 the FDA knew that this device had ten times more migrations
8 than our predicate Simon Nitinol filter. We gave all that to
9 FDA.

10:43:43 10 THE COURT: Well, it seems to me if they do that,
11 Mr. Lopez, there's two things you do in response. One is you
12 either put on evidence or argue to the jury if it's true that
13 there's zero evidence they sent anything to the FDA, where are
14 the documents, they haven't shown them to you, jury.

10:43:59 15 And, number two, you put on your expert, which I
16 think you're planning to do, to say that the FDA's inaction
17 isn't approval, the FDA doesn't step in and tell people to
18 take adulterated things off the market, that is an
19 independent legal obligation.

10:44:16 20 MR. LOPEZ: Right.

21 THE COURT: You put on your side of that case.

22 MR. LOPEZ: Well, yes, Judge, we're prepared to do
23 that.

24 THE COURT: And the problem I'm having is with the
10:44:23 25 notion that I should tell them you can't make that argument,

10:44:26 1 you can't present that evidence because the plaintiffs can't
2 rebut it as fully as they would like to.

3 MR. LOPEZ: Okay, Judge, I'm going to focus on one.
4 You asked me what it is I want you -- that I think is unfair,
10:44:38 5 and the kind of evidence that I think is irrelevant.

6 So what if they reported it all. Let's assume they
7 perfectly reported every one of their adverse events. And
8 when the FDA came in in 2015, they said, By the way, you've
9 done a great job, you accurately reported every adverse event
10 that ever happened, you categorized it right, you didn't hide
11 anything, and you sent it all to FDA. So what? What's the
12 relevance of that?

13 THE COURT: Isn't that directly relevant to your
14 allegation that they acted negligently and that they acted
10:45:09 15 with bad intent and evil mind?

16 MR. LOPEZ: No. How can it be? The evidence is
17 going to be that they put -- everything that they were
18 required to submit all the deaths for the Recovery filter, all
19 the caudal migrations for G2 filter, they all got sent to FDA.
10:45:28 20 And FDA -- what they're going to imply, I've heard it before,
21 FDA had all this. FDA trends. FDA pays close attention to
22 this kind of stuff. We follow FDA's direction with everything
23 we did.

24 I mean, I don't -- I have no evidence to dispute
10:45:49 25 that.

10:45:49 1 THE COURT: Well, but see, you're sort of shifting
2 between on one hand saying it's not relevant, and on the other
3 hand saying you can't dispute it.

10:45:59 4 MR. LOPEZ: Well, that just means there's two reasons
5 not to let that in.

10:46:13 6 THE COURT: But I have great difficulty with the
7 notion that -- what they will clarify -- characterize as their
8 careful compliance with the legal requirements of getting
9 approval is evidence that they didn't act negligently and
evidence that they didn't act with bad faith, intent, and
malice. I think that is directly relevant to that.

10:46:30 12 Now, you might disagree with me, but that's why I
13 denied your *Cisson* motion.

10:46:45 14 The other side of that, that you can come back to
15 again, that I'm trying to wrestle with, is this notion that
16 they shouldn't be allowed to make those arguments because
17 you're not able to rebut it effectively because you couldn't
18 get discovery from the FDA.

19 MR. LOPEZ: Right, that's one of the arguments.

10:46:45 20 THE COURT: Well, it seems to me there's two
21 arguments. That's one of them. And the other argument you've
22 made is that this silence by the FDA is hearsay.

23 MR. LOPEZ: That's one -- that's --

10:46:58 24 THE COURT: And they can't present evidence of it
25 because it violates the hearsay rules.

10:47:00 1 MR. LOPEZ: That's one of them.

2 THE COURT: Is there more?

3 MR. LOPEZ: Well, the more is the -- how misleading
4 and unfair it is -- Judge, we're not -- we don't have time to
10:47:11 5 do this. We could do this if we had more time. We could show
6 all the times they misreported, didn't report,
7 mischaracterized. We probably don't have time to do that in
8 this case.

9 The fact that they reported all of these adverse
10 events to FDA is a gigantic "so what" in this case, because
11 it's not what they told FDA about those things -- first of
12 all, we don't even know who they mean at FDA. For all we
13 know, these things get sent to FDA, we don't know, and it
14 goes to some process, data entry person, and it gets shipped
10:47:51 15 off to the MAUDE database, and not one person at FDA looks at
16 any of those and analyzes them. There's no evidence that
17 that happened in this case, that the FDA gathered up
18 committees and grabbed all these adverse events and said,
19 Let's look at this and see if this company is selling an
10:48:07 20 adulterated or misbranded product, or whether or not we
21 should send them a letter that says you should consider
22 redesigning this or taking it off the market.

23 So the issue in this case is not what they may have
24 reported about the postmarket performance of their device to
10:48:24 25 FDA; it's what did they tell the doctors? What did they --

10:48:28 1 what did they put out in the real world? The people -- the
2 real folks that need to know about this, and whether or not
3 it was given a reasonable chance to get to the plaintiff,
4 Shari Booker.

10:48:48 5 I mean, even if we were to stipulate that everything
6 was appropriately reported and sent to FDA, I mean, okay.
7 But that doesn't mean they did their job with respect to
8 Dr. D'Ayala, her subsequent treating --

9 THE COURT: It's a great jury argument. That point.

10:49:09 10 I just can't see that -- it seems to me the three
11 arguments you've made, that I have not yet disagreed with,
12 the first one was the relevancy, that I don't agree with.
13 The other three are that this there is this imbalance in
14 discovery because you couldn't get FDA depositions and you
15 couldn't subpoena them; second, this notion that the FDA
16 silence is hearsay; and the third that I think you just made
17 is that you think the assertion is misleading when they claim
18 we sent everything to the FDA before --

19 MR. LOPEZ: Right. Because we don't know what
20 happens at the other end.

21 THE COURT: Okay. I understand those issues.

22 MR. LOPEZ: Okay. Just one more.

23 THE COURT: All right.

24 MR. LOPEZ: And, again, we'll try to squeeze the
25 real -- what we think is the real evidence in the case into a

10:49:53 1 very short period of time, and we're trying to do that.

2 Then one of the reasons there's -- these are
3 considered a mini trial, I mean, we have documents that show
4 the state of the FDA during this period of time was in a --
10:50:08 5 in that department there's a GAO report that says that the
6 FDA was incapable of dealing with adverse events and
7 premarket approvals, premarket clearances, and postmarket
8 surveillance.

9 I'm hoping the Court is going to allow to get in
10 that kind of evidence if, in fact, there's some innuendo,
11 there's some type of suggestion by the defendants that this
12 FDA -- that there's an FDA that sits there in wait for the
13 next MDR to be reported by Bard to see whether or not there's
14 a problem with the device.

10:50:48 15 Those are the kinds of things I'm concerned about,
16 Judge. Is the jury being given a false impression that
17 somehow or other the FDA is diligently and vigilantly looking
18 at all of this data as it comes in, and the fact that they
19 just sat there and did nothing, in some instances for 12 or
10:51:07 20 13 years, means that the FDA must have blessed this thing.

21 THE COURT: Okay. I think I understand the points
22 you've made.

23 MR. LOPEZ: Thank you, Your Honor.

24 THE COURT: Defense counsel.

10:51:20 25 MR. NORTH: Your Honor, respectfully, I would take

10:51:23 1 issue with Mr. Lopez's claim that he cannot rebut the
2 evidence. There is a written record taller than I am of
3 documentation sent to the FDA. That's what my witnesses will
4 be testifying about. It's all in the written record. It was
10:51:38 5 submitted for -- as a part of the preemption motion. The
6 communications are there. It's not just some witness getting
7 on the stand and saying, I sent everything. It is documented
8 completely.

9 He also has all of the tests we performed. He has
10:51:55 10 million pages of tests and e-mails and references and
11 communications. He's got all the evidence in the world. If
12 he thinks we hid something from the FDA, he can ask --
13 cross-examine our witnesses, Here's the document, why didn't
14 you give that test to the FDA? He's got all of the materials
10:52:13 15 he needs.

16 With regard to the FDA's inaction, we believe that
17 we are entitled just to say we gave the FDA this
18 information -- he can challenge that if he wants to -- and
19 the FDA never recalled the product.

10:52:29 20 First of all, as we cited in the pretrial order,
21 there is a Georgia case right on point, *Browning versus*
22 *Paccar*, that talks about with regard to a mass-produced
23 product that is under the auspices of an agency that has the
24 authority to recall that product. The absence of a recall is
10:52:50 25 some evidence going into the risk utility reasonableness

10:52:55 1 equation.

2 And for much the same reason, or same rationale that
3 I believe the Court articulated here in denying the
4 plaintiffs' motion in limine based on *Cisson*. At bottom it
10:53:09 5 sounds to me like Mr. Lopez is asking this Court to
6 reconsider its ruling on his Motion in Limine Number 1, and
7 for the reasons that we argued in response to that motion and
8 for the reasons set forth in this Court's order, we would ask
9 the Court to adhere to that ruling.

10:53:26 10 I'm happy to ask -- to answer any questions that the
11 Court may have.

12 THE COURT: Okay. Thank you.

13 All right. Well, here are my conclusions on this
14 issue, Counsel. As I've already indicated, I believe that
10:53:40 15 evidence by the defendants that they sought to comply with
16 regulatory obligations is relevant. I think it's relevant to
17 the negligence claim. I think it's relevant to the punitive
18 damages claim. May be relevant to other issues as well. So
19 I'm not going to exclude it on relevancy grounds.

10:54:03 20 With respect to the argument from plaintiffs that it
21 is misleading because the plaintiffs don't believe that Bard
22 was as transparent and as forthcoming as it ought to be, I
23 think that is fair game for a jury trial, and that the
24 defendants can present evidence as to why they thought Bard
10:54:24 25 was not forthcoming. In fact, that has been a lot of what

10:54:27 1 this case has been about, at least in the portions I've seen
2 in the motions, and what wasn't told to the FDA, and that the
3 FDA wasn't a good reviewer of information in any event.

4 So I don't think there is a basis to exclude it as
10:54:43 5 misleading. It's the defendants' side of the case. The
6 plaintiffs think it is misleading and can seek to prove that
7 to the jury. That is not a basis for excluding it.

8 As to the argument that the FDA's silence is
9 hearsay, I am not going to limit now any testimony from the
10 defense on that point, but the argument can be made at trial.
11 And the reason I'm not going to now is because I think the
12 cases are fairly narrow in saying that when a person in an
13 exchange intends silence to be an assertion, it is an
14 assertion by that person for purposes of the hearsay rule. I
10:55:03 15 don't believe that the FDA views its inaction as an assertion
16 of anything. And I don't think, therefore, that its inaction
17 is hearsay within the meaning of this rule.

18 Now, that could be different in a specific context.
19 And if there is a point where you believe, Mr. Lopez, or
10:55:48 20 plaintiffs' counsel do, that the silence that the defendants
21 are seeking to communicate to the jury was intended to be an
22 assertion by the declarant, namely the FDA or anybody else,
23 you can object. And if I agree with you, it will be hearsay.
24 But that has to be the context in which it is hearsay, in my
10:56:10 25 judgment.

10:56:11 1 The last argument that the defendants -- or the
2 plaintiffs made was a more general argument that there is an
3 imbalance here because Bard can talk about everything it
4 shared with the FDA, and the plaintiffs are hobbled because
10:56:25 5 they can't test that through discovery of the FDA in
6 depositions or subpoenas. I understand that issue. We've
7 talked about that before in that case. It's been present all
8 along.

9 But it does appear to me that what has happened in
10 this case is that there has been considerable discovery done
11 on Bard's communications with the FDA. Plaintiffs have been
12 thorough in deposing every witness who claims to have
13 communicated with the FDA, and obtaining every document that
14 was shared with the FDA, and identifying lots of evidence
10:56:58 15 that the plaintiffs was not shared with the FDA in doing FOIA
16 requests of the FDA and bringing forward experts who will
17 opine about what the FDA does and does not do.

18 Given that state of the record, I cannot conclude
19 that there is such an imbalance of available information in
10:57:18 20 this case that I should foreclose the defendants from making
21 their FDA defense for all of the reasons I stated in ruling
22 on the *Cisson* motion.

23 So at this point I'm not going to foreclose any of
24 that. But I will rule on objections. As we're going through
10:57:34 25 the trial, if you think I'm missing the point, ask me for a

10:57:38 1 sidebar and we'll have a sidebar so I make sure I understand
2 the point before I rule on it.

3 While we're on that point, let me mention, during a
4 trial, your objections should not be speaking objections.

10:57:48 5 Stand up and say, you know, "Objection. Hearsay."

6 "Objection. Relevancy." If I don't understand what you're
7 objecting to, I'll ask you for more clarification. If you
8 don't think I understand, you can ask for a sidebar. What I
9 don't want to do is end up having a debate with you in front
10 of the jury, which I think can lead to information being
11 shared with the jury that really should be kept at sidebar.

12 MR. LOPEZ: I think that is bringing back memories
13 for both Mr. North and I when we tried our case in front of
14 Judge Jones. We had one sidebar.

10:58:23 15 THE COURT: One?

16 MR. LOPEZ: One. In fact, at the end of it, he goes,
17 Why are we at sidebar?

18 THE COURT: Well, my son-in-law clerked for
19 Judge Jones, so I understand his point.

20 MR. LOPEZ: And, Your Honor, just on that, before you
21 leave that, there was one thing Mr. North said and I don't --
22 I don't want to have to wait, but I think he gave an example
23 of the type of thing I think he probably shouldn't be able to
24 say, and that is, We gave it all -- the FDA took no actions to
25 recall this device.

10:58:51 1 I mean, I don't think he should be able to say that.
2 I mean, that's going to open up -- you're going to need to
3 give me two or three more days to try this case if that's the
4 kind of stuff that comes in.

10:59:02 5 THE COURT: Well, I know that's your view. I'm not
6 going to agree with you now. And when we get there, if I
7 think you're right in the context of trial, I'll sustain it.

8 And incidentally, on the length of the trial, which
9 has been alluded to a couple times here, I do want to remind
10 everybody that we agreed these were three-week trials to
11 begin with. I am absolutely confident you can use every
12 minute of a six-month trial if we let you do it. I know you
13 could. You could go on forever about this.

14 What I'm trying to keep in mind is we're going to
15 have nine citizens in this box who will try, through three
16 weeks of evidence, to keep track of everything, and I am
17 absolutely persuaded that a fourth, fifth, or sixth week
18 wouldn't make a difference in how this case come out. You
19 know better than I do, there is only so much a jury can
20 absorb. And if we run down every rabbit trail in this case,
21 we will waste time and we won't help get a fair result.

22 And on that point, I just have to say it, I know
23 you're protecting the record and your flexibility, but almost
24 8,000 exhibits? I have never seen a trial where the outcome
25 turned on more than ten or 15 exhibits. Maybe 20. But you

11:00:27 1 guys know the ability of a jury to absorb this.

2 So my plea for the jury is: Please don't put 500
3 documents in evidence. They can't do anything with that.
4 They can't go back to the jury room and review that in less
11:00:39 5 than four, five days. Let's do our best to focus on what
6 really is pivotal for purposes of the jury's deliberation.
7 You all know that already.

8 Okay. Well, that was quick. We got through the FDA
9 issue pretty quickly.

11:00:58 10 Let's turn to page 25, where the issue raised in
11 paragraph E, again by the plaintiff -- I'm sorry, by the
12 defendant, defendants, is whether the plaintiff can present
13 the testimony of defendants' withdrawn expert witnesses.

14 The question I have for plaintiffs' counsel first
11:01:20 15 is: Do you intend to present testimony from withdrawn
16 experts, and if so, what? What is it you're going to try to
17 present from that?

18 MR. O'CONNOR: Your Honor, I'll address that.

19 First of all, let me give you background. We got --

11:01:38 20 THE COURT: Pull the mic over.

21 MR. O'CONNOR: Do you want me to step up there?

22 THE COURT: Either way. There's folks on the phone
23 who won't hear unless you're speaking pretty directly into the
24 mic.

11:01:47 25 And the question I have is not for long argument.

11:01:51 1 Just what is it you want to present from withdrawn experts in
2 general.

3 MR. O'CONNOR: From their experts?

4 THE COURT: From the experts that have been
11:02:00 5 withdrawn. The three specific ones that are mentioned in the
6 Final Pretrial Order, Moritz, Rogers, and Stein.

7 MR. O'CONNOR: Well, specifically, I think all three
8 are going to testify about reasonable expectations and what
9 they would expect from a company like Bard, and what they
11:02:14 10 didn't receive.

11 THE COURT: Okay. And they said that in the
12 depositions, and you want to use that at trial?

13 MR. O'CONNOR: You know, Your Honor, I'm most
14 familiar with Dr. Moritz, but we went through quite a bit of
11:02:26 15 detail about what he would expect and, in fact, what he did
16 and did not receive to render his opinions in this case. And
17 at the end of the deposition, he testified that based upon his
18 review of everything, including the literature and our
19 experts' reports, he now has concerns about Bard filters.

20 And so we think that that testimony goes directly to
21 the issue of what doctors in different disciplines expect out
22 of companies like Bard in terms of the information they
23 should receive, including the whole issue about increased
24 failure rates and things like that.

25 THE COURT: Okay. I'm going to let you address the

11:03:05 1 argument in a minute. I just wanted to understand what you
2 were intending to use them for so I understood the issue.
3 I'll give you a chance to respond. This is defendants' issue
4 so I want to let them argue that.

11:03:18 5 As you're sitting down, and as, Mr. North, you're
6 standing up, here is a general question that occurred to me
7 on this issue, and I haven't looked at the case law enough to
8 know if it's addressed, but the argument is hearsay, that
9 their testimony is hearsay, and that it's not an admission of
11:03:37 10 a party opponent, therefore -- but why doesn't that come in
11 under prior testimony of an unavailable witness? 804? And
12 Rule 32, which says if the witness is unavailable his
13 deposition can be used for any purpose at trial. It's
14 32(a)(4) and it's 804(b)(1). Why do we even have to talk
11:03:59 15 about whether it is an admission of a party opponent?

16 MR. NORTH: I'm trying to absorb that. I mean, I
17 spent last night reading *Glendale Federal Bank* and the Third
18 Circuit's decision on this on *Kirk*, this issue, and none of
19 them raised that point or address that.

11:04:17 20 THE COURT: I saw that. In fact, I found an article
21 from the Federal Lawyer that tracks every circuit's law on
22 this, and there's a split, as you know.

23 MR. NORTH: Right.

24 THE COURT: Never mentions 804 or Rule 32. Maybe I'm
11:04:30 25 just missing something. But if these experts are beyond the

11:04:33 1 subpoena power of the court, and I assume they're more than
2 100 miles from this courthouse, and they won't come here at
3 the behest of plaintiffs, aren't they unavailable for purposes
4 of Rule 804, and don't we therefore get to use their testimony
11:04:50 5 as an unavailable witness under 804(b)(1)?

6 MR. NORTH: I think you have thrown me a curve ball.
7 For some reason I'm thinking there's got to be a rationale. I
8 mean, surely every court in the country that has dealt with
9 this has not overlooked that. Although I guess it's possible.

11:05:14 10 THE COURT: Well -- and maybe this is something you
11 need to look into, but we can talk about the 801 evidence, but
12 the Rule 32(a)(4) is titled "Unavailable Witness," and it
13 says: "A party may use for any purpose the deposition of a
14 witness, whether or not a party, if the court finds," and then
11:05:35 15 there's a list:

16 " (A) the witness is dead;
17 " (B) that witness is more than 100 miles from the
18 place of hearing or trial or is outside the United States,
19 unless it appears that the absence was procured by the party
11:05:48 20 who wants to use the deposition;

21 " (C) the witness cannot attend because of illness,
22 infirmity, death," et cetera. Or there is exceptional
23 circumstances.

24 And that squares with Rule 804(b)(1), which says
11:06:04 25 that if a witness is unavailable, then prior sworn testimony

11:06:09 1 is not hearsay.

2 MR. NORTH: Could I ask the following, Your Honor,
3 indulgence. Could the Court give us to Tuesday to look into
4 this issue? In light of -- I mean, the Court obviously raises
11:06:24 5 a very good point. I'm curious why the federal court of
6 claims in *Glendale* and the Third Circuit in the *Kirk* case have
7 not addressed this or looked at it from that angle. If we
8 could have until Tuesday to file a two-page summary or
9 something with the Court setting forth our position if we see
11:06:43 10 some way to reconcile those two.

11 THE COURT: Sure.

12 MR. NORTH: If we don't, that may be the short answer
13 to it.

14 THE COURT: Okay. Yeah. That's fine.

11:06:51 15 MR. NORTH: Thank you, Your Honor.

16 THE COURT: And you can do the same thing,
17 Mr. O'Connor. By the close of business Tuesday, a two-page
18 memo on whether you agree that 804(b)(1) and 32(a)(4) govern
19 this situation.

20 If for some reason they don't, I don't know what
21 that reason is, but if they don't, then I've got to deal with
22 the 801 cases, the agent cases. I know what they are. I
23 know the *Hanford* case is probably the key case in the
24 Ninth Circuit. I know it looks to the *Glendale* case. And
11:07:22 25 I've got an article that I found that tracks every circuit's

11:07:25 1 law on that. So we can go through that law and decide
2 whether we think these experts are agents for purposes of
3 that rule. But it seems to me we don't need to get there if
4 they're unavailable. It's not hearsay and it can be used.

11:07:39 5 Any question, Mr. O'Connor?

6 MR. O'CONNOR: No, Your Honor. That makes sense. We
7 were prepared to talk about that today.

8 Just a comment. As you know, these depositions were
9 taken quite a while ago, but we can get you what you need by
11:07:54 10 next week.

11 THE COURT: Okay.

12 All right.

13 MR. O'CONNOR: Exactly when did you want that again,
14 Your Honor?

11:07:59 15 THE COURT: By the close of business on Tuesday.

16 MR. O'CONNOR: Thank you.

17 THE COURT: All right. Page 27 of the Final Pretrial
18 Order raises the question of whether sales and marketing
19 evidence is admissible. And this goes to, as I understand it,
21 some marketing people who were deposed by the plaintiffs and
that had been listed as witnesses in the case.

22 The question that I want to ask plaintiffs before I
23 hear defendants' argument is: What exactly do you intend to
24 present from the sales and marketing individuals, and why is
11:08:52 25 it relevant to Ms. Booker's claim?

11:08:57 1 MR. O'CONNOR: I'll respond to that, Your Honor.

2 Your Honor, just by going back, early on I think you
3 limited the parties to discovery of just the regional people.
4 And in what was learned by taking the depositions of these
11:09:19 5 regional managers is that they specifically received
6 instructions on what doctors and their sales force
7 communicate to doctors, but they also did not receive a great
8 deal of information, such as what Bard was aware of when it
9 came to increased failure rates. When Bard was aware of
11:09:45 10 problems and difficulties and dangers associated with the
11 filters, those weren't communicated to the sales people
12 through the regional people. And that testimony has been
13 developed quite extensively in the depositions.

14 Now, two of the people that were deposed,
11:10:04 15 Mr. Cortelezzi, and then Robert -- Daniel Orms, are both
16 regional managers, and at different times they were the
17 managers of Mr. Ferrara's, the sales rep in this case, of his
18 region. So their testimony goes right to the heart of the
19 issue of how Bard kept the medical profession in the dark by
11:10:28 20 not communicating information that was harmful to Bard to its
21 sales force, and that prevented the sales force, who have
22 said that they would expect the company to give them full,
23 complete, accurate, and truthful information -- and we have
24 testimony when they were shown certain things, they have
11:10:46 25 agreed that they didn't receive that, and perhaps that would

11:10:50 1 have been helpful to continue the relationships that doctors
2 expected of them and relied upon them to be truthful and
3 honest and accurate about filters.

4 So it goes to a number of issues, everything from
11:11:06 5 failure to warn, but also punitive damages.

6 THE COURT: Okay. I understand that.

7 Now let me hear the defense argument as to why it
8 should not be admitted, and then I'll be happy to hear your
9 response, Mr. O'Connor.

11:11:19 10 MR. NORTH: Thank you, Your Honor.

11 When the plaintiffs began designating depositions,
12 we were quite surprised to see, I think there were eight or
13 nine sales or marketing personnel who have been designated as
14 a part of the 38 depositions they've designated. This
11:11:35 15 includes multiple sales representative who never met the
16 doctor, Dr. D'Ayala, who implanted the filter in Ms. Booker.

17 They designated this testimony about what these
18 people knew, what they didn't know, what they received, what
19 they didn't receive. But there is no tie to any of this
11:11:54 20 testimony to the claims in this case.

21 The Court has already granted summary judgment on a
22 misrepresentation claim anyway. And the evidence is clear,
23 Dr. D'Ayala testified he didn't recall ever talking with a
24 sales representative. He testified he didn't recall ever
11:12:12 25 seeing any marketing material.

11:12:14 1 So we're having a very difficult time seeing any
2 causal link with, for example, what Jason Greer, a sales
3 representative in Memphis, Tennessee, what he received or did
4 not receive, what he told doctors or did not tell doctors.

11:12:29 5 What relevance that has to whether we properly designed the
6 filter and properly warned Dr. D'Ayala. If he didn't
7 remember ever talking to a sales rep, if he didn't remember
8 ever seeing any marketing material, there is no basis as to
9 why that would ever feed into the warning claim.

11:12:52 10 We think this is applicable, this issue, to a large
11 number of the deposition designations that were provided to
12 the Court, I guess either last night or this morning, and we
13 think it is going to be a recurring issue with the Court or
14 during the trial, and we just want to flag the issue for the
11:13:05 15 Court's -- to be aware of it.

16 THE COURT: Let me ask you a question, Mr. North.
17 Did the doctor say "I didn't talk to a sales rep" or "I don't
18 remember if I did or not"?

19 MR. NORTH: If I could ask Ms. Helm, I think she
11:13:29 20 could probably clarify that with greater accuracy.

21 MS. HELM: Your Honor, I don't have the transcript
22 right in front of me. My recollection is he said "I don't
23 recall ever speaking with him." But I would be happy to go
24 outside and get the internet and pull up the transcript.

11:13:42 25 THE COURT: Okay. No need to do it yet. We'll come

11:13:45 1 back to that.

2 Okay. Thanks.

3 Mr. O'Connor.

4 MR. O'CONNOR: So, Your Honor, setting aside what may
11:13:58 5 or may not have been communicated to Dr. D'Ayala in this case,
6 the testimony has been, and it's come across strong, that the
7 sales force was the face of Bard. That they were the most
8 effective way to communicate to the doctors. And -- and that
9 the -- they had every opportunity to communicate, not just the
11:14:26 10 good, but also the bad when they knew about it, through their
11 sales force. The sales force knew how to reach doctors, they
12 developed relationships with doctors, and every doctor who
13 used the Bard filter knew who his sales representative was.

14 So it's very important testimony and it goes right
11:14:46 15 to the heart of many issues in this case. But when Bard was
16 aware of problems it had with its filters, it knew, but made
17 a choice not to let the sales force have that information and
18 make every effort to communicate directly to the doctors.

19 And it also goes to an issue of labeling,
11:15:09 20 Your Honor, because it's not just what is done in certain
21 documents, but it's how the company positions itself, how it
22 strategizes, how it communicates, in so many different
23 avenues, information, both the good and bad, about its
24 filters.

11:15:24 25 So that's why we believe that the regional sales

11:15:29 1 force people are absolutely critical and important witnesses
2 to this case, and that they will help this jury understand
3 what Bard was capable of doing, what opportunities Bard had
4 and the choices Bard made not to use this very important
11:15:48 5 voice.

6 THE COURT: Okay. Thank you.

7 I am not going to foreclose the plaintiffs from
8 presenting sales and marketing evidence. I think a
9 distinction you made, Mr. North, is relevant. I've knocked
11:16:02 10 out the misrepresentation claim. So what was actually said
11 to the doctor and whether or not it was misleading is not in
12 the case.

13 What is in the case is a failure to warn. And it
14 seems to me the fact that sales personnel who are either not
11:16:21 15 advised of or as a practice did not disclose things that the
16 plaintiffs claim should have been disclosed to the doctors as
17 warnings goes directly to the failure to warn claim. I think
18 it's relevant, and so I'm not going to exclude it.

19 All right. Let's turn to pages 48 and 49 of the
11:16:51 20 Final Pretrial Order.

21 Actually, let's take up the paragraph that's on
22 pages 47 and 48 first. And this concerns two issues. One is
23 if -- if deposition testimony from a witness is being
24 presented to the jury by one side, should all of what that
11:17:50 25 witness's deposition testimony ultimately will be, be shared

11:17:55 1 at that point in time? Or can a party presenting it just
2 limit it to what that party wants to present? In other
3 words, if they're going to put on deposition testimony from
4 Witness A, do we have to let the jury hear everything that's
11:18:08 5 coming in on Witness A's deposition, including what the
6 Defendants want?

7 Let me tell you my reaction to that and get your
8 thoughts.

9 The rule which says that an opposing party can
11:18:21 10 counterdesignate deposition testimony or parts of a document
11 that it feels in fairness ought to be presented to the jury
12 to me is presented -- or exists to present misleading
13 evidence from being presented to the jury. And I view it
14 narrowly, not broadly. So that if the plaintiffs are playing
11:18:42 15 excerpts from a deposition and the defense believes if you
16 don't add the rest of that answer it gives a misleading
17 impression of what the answer is, then the plaintiffs can be
18 required to include the rest of that answer.

19 What it does not allow, in my judgment, is for the
11:19:01 20 defendants to force the plaintiffs to play to the jury
21 everything in the deposition that the defendants like and
22 thinks helps their case.

23 So my view would be that if there are excerpts that
24 are needed to be included to make the testimony not
11:19:18 25 misleading and complete, those should be played when the

11:19:22 1 plaintiffs present their evidence, but everything else should
2 be reserved for the defendants' case rather than trying to
3 play everything to the jury at that point in time.

4 Now, with that reaction from me, I'm interested in
11:19:36 5 your thoughts.

6 That takes a little work. You're going to have to
7 confer about what's in and what's out. I really don't want
8 to have to make decisions on all of those excerpts. But it
9 also means that we shouldn't just have the defendants say,
11:19:47 10 Okay, play this 20 pages of additional material as well, even
11 if you take credit for the time, because I don't think that's
12 the intent of the rule.

13 MR. LOPEZ: Your Honor, we all agree this is the most
14 fun part of the case, is doing the deposition, counters, and
11:20:03 15 objections. I'm being facetious.

16 THE COURT: I know.

17 MR. LOPEZ: It's a tedious thing.

18 THE COURT: I really love it. I don't know why you
19 don't.

11:20:10 20 MR. LOPEZ: Now you get to have fun with them.

21 But here's what I would propose, is this: We've
22 designated more than one to be able to play in the time we
23 have. We have done that because we don't know whether we're
24 going to get a live witness or not a live witness. In some
11:20:27 25 of these, the counters by the defendants technically are

11:20:30 1 beyond the scope of making it complete. In other words,
2 beyond a fairness thing.

3 We would like an opportunity to look at those and
4 see if we can agree. Maybe there's only two or three
11:20:40 5 additional things that may be considered assertion by them
6 that they should play in their own case. I think we can sit
7 down with them once we narrow the scope of what depositions
8 that we actually believe we're going to be able to get into
9 evidence and the ones we have time to play. I think we can
11:20:57 10 probably narrow the scope of some of what it is we would ask
11 you to take out of the plaintiffs' case and make them put in
12 the defense case, which may make us take out some of our
13 affirmatives and actually make them counters to their
14 assertions.

11:21:12 15 We haven't done that yet, but it is something we are
16 going to do and we need to do. I don't know whether the
17 defendants have a different idea about that. But I think
18 with Your Honor's guidance, which you just gave us, it helps
19 us now have that kind of a meet and confer and maybe make the
11:21:30 20 problems a lot smaller than it might be currently.

21 THE COURT: Okay. Thank you.

22 Defenses counsel, your thoughts.

23 MR. NORTH: One second.

24 Your Honor, we understand the Court's interpretation
11:21:55 25 of the rule of completeness. Our only concern is that, and

11:22:00 1 as Mr. Lopez just indicated, thankfully, they're not going to
2 play every deposition they've designated. But if they are
3 going to play a large number of depositions, it's just going
4 to be difficult to -- for us because we're going to have to
11:22:14 5 sort of repeat some things, who the person is, to reorient
6 the jury to have the rest of the testimony played in our
7 case. So it's a logistical issue that I think is a
8 challenge.

9 THE COURT: I agree. I think it is. But I think I
11:22:31 10 want to go with the approach that I believe is accurate under
11 the rule. That may mean you need to take 30 seconds to
12 reorient the jury as to who the witness is. I think you just
13 have to do that when it comes to depositions. I think that is
14 better -- especially because, I suspect, in the second and
11:22:48 15 third week of the trial, some of the stuff that seemed to
16 really matter a lot in the first week will become less
17 important, and we may spare the jury some of that deposition
18 testimony.

19 So let's have you confer about that. I think you
11:22:59 20 ought to be able to work those issues out. If you come to an
21 impasse on something, I'll be happy to address it.

22 MR. LOPEZ: Do you want all of these by a certain
23 time?

24 THE COURT: Well --

11:23:06 25 MR. LOPEZ: Sometimes you don't make a decision until

11:23:12 1 maybe --

2 THE COURT: Well, that raises a different question.

3 MR. LOPEZ: Okay. Go ahead.

4 THE COURT: I received -- I need to get Mr. North's
11:23:22 5 attention.

6 MR. NORTH: I'm sorry.

7 THE COURT: It's okay.

8 I received these yesterday. And as I look through
9 them -- and what I'm holding up, for those listening in, are
11:23:30 10 two black books with 45 tabs. As I look through them,
11 there's no deposition excerpts in here. What we've got in
12 here are tables that list pages, and then a lengthy
13 description of an objection.

14 What are you expecting me to do with these books?

11:23:56 15 MS. HELM: Your Honor, I think the direction from
16 your office was that we were supposed to get the objections to
17 you with the page and line numbers by yesterday, but the
18 highlighted transcripts are coming to the Court today.

19 THE COURT: Well, what -- what -- are you saying you
11:24:14 20 think I should rule on every objection that's in these books?

21 MS. HELM: Actually, Your Honor, I think if you look
22 under each tab, there's a large majority of objections that
23 are -- relate to the same subject matter, and some of which,
24 frankly, your rulings yesterday addressed and -- and we
11:24:32 25 weren't able to go back and address our objections after we

11:24:38 1 got your ruling yesterday. That was already in progress.

2 So I think if the Court looks, there's a whole
3 section that relates to the ruling on our Motion in Limine
4 Number 1, and we're going to have to go back and look at our
11:24:52 5 objections based on the Court's ruling.

6 THE COURT: Well, I think what I said at the last
7 hearing was that what I need to get from you are -- well, two
8 things: I need deposition transcripts for when the
9 depositions are being read to the jury, if any deposition is
11:25:08 10 going to be read. And if they're being read, I'll rule on
11 objections as they come up.

12 The second thing I think I said I needed was
13 deposition transcripts where there's an objection you want me
14 to rule on before a videotape is created. I need the
11:25:23 15 transcript. I need the objection highlighted in red so I can
16 read it and rule yes or no on it.

17 But I can't do that on a thousand objections. I
18 can't do that on 300 objections. It seems to me that this --
19 I appreciate you doing this, but I don't know what I do with
11:25:40 20 these books. I can't look at the objection here and make any
21 ruling. I've got to look at the objection in the transcript
22 to rule. And I'm hoping that most of those don't require
23 rulings. And it sounds as though you're going to be
24 narrowing down significantly what is going to be presented in
11:25:59 25 any event.

11:26:00 1 So in terms of the question you just asked,
2 Mr. Lopez, about when does this happen, it can't be done on
3 this basis. And if there are comparable books like this full
4 of deposition transcripts, I don't have time to go through
11:26:14 5 them and rule on every objection, particularly when I think
6 it's true that some of this has been resolved with my other
7 rulings and that half of this is going to disappear before we
8 ever present it to the jury.

9 So I guess the question becomes when can your
11:26:30 10 videographers or your videotape editors get the work done?
11 If you know when we get together on March 14th that you
12 definitely want to play 20 pages of somebody's deposition on
13 the morning of March 16th, and you can get me the transcript,
14 I'll go through it that night and tell you what I affirm and
11:26:51 15 what I deny on objections, and your videographer will have a
16 day to put it together.

17 MR. LOPEZ: I mean --

18 THE COURT: I think that may be the best way to do
19 it, because you're going to know as you go along what you're
11:27:04 20 going to present, and it's going to get shorter and shorter as
21 you go through trial. If you think that's wrong --

22 MR. LOPEZ: I -- no, I think that's right. But I
23 think what we were doing is what we thought we had to have
24 done by today and -- but I agree with you. There's no reason
11:27:20 25 for you to now look at 10 hours, 11 hours, 12, whatever it is

11:27:25 1 now of depositions, when I know that we're not going to be
2 able to play more than four or five.

3 But then again, some of these, like 20 minutes could
4 be 14 by the time you rule. So -- I mean, I like the idea of
11:27:42 5 telling you, Your Honor, we're going to play four, five
6 videos tomorrow, here is what we proposed, here are their
7 counters, and here are our objections, and having you rule on
8 those. You know, I mean, we can get our videographer to
9 change those tapes pretty quick. Maybe not the night before,
11:27:57 10 maybe two nights before so -- because that is not easy. You
11 have to take out -- sometimes you have to take out exhibits.
12 You may sustain an objection to the use of an exhibit.

13 Could we confer -- we both feel what you're feeling
14 about this, believe it or not. And can we confer on this and
11:28:15 15 maybe propose something to the Court about how to deal with
16 these? Maybe more closer to real time and not only real
17 time, but the real -- what we really do want to offer in
18 evidence. Some of it's going to depend on the live
19 witnesses. We may pull back two or three of these, depending
11:28:34 20 on the availability on certain dates of certain live
21 witnesses.

22 So whatever is easiest for the Court we'll do. I
23 have no problem with the suggestion that you have, and I
24 don't blame you for not wanting to do that. But -- because a
11:28:46 25 lot of that stuff is going to be withdrawn or pulled back

11:28:48 1 anyway based on your MIL ruling, and, frankly, based on some
2 of the discussions we've had today.

3 THE COURT: Okay.

4 MS. HELM: Your Honor, I just -- to the extent that
11:28:58 5 we all misunderstood the direction from the Court and our
6 contact with your staff, we were all under the impression that
7 that's what we were supposed to give you today, and that the
8 deposition -- yesterday, and the deposition transcripts were
9 supposed to come in today. But we'll go back and address it
11:29:16 10 properly.

11 THE COURT: I'm sorry if we gave you inaccurate
12 descriptions, because this is not what I need and this was a
13 lot of work. But I can't really do anything with these books.
14 I can't rule on any basis without looking at the testimony.

11:29:31 15 MS. HELM: And, Your Honor, I believe based on
16 direction from your staff, you're going to get all of the
17 depositions today, full-size transcripts, printed double-sided
18 front and back on a page, highlighted. So if we need to stop
19 that process, I need to stop it --

11:29:49 20 THE COURT: Stop the process.

21 MS. HELM: Okay. But that was the direction --

22 THE COURT: I'm sorry. I'm sorry you got that
23 direction because that's a waste of time.

24 MS. KOWALZYK: Can I ask one more clarification. It
11:30:00 25 sounded to me like when you were talking about what you

11:30:03 1 expected, you expected highlighted transcript with the
2 objections in red on the transcript?

11:30:14 3 THE COURT: Yeah. That way I can flip through a
4 transcript, I can stop at every objection that needs a ruling,
5 I can dictate my ruling, and I can go on. And I can get you
6 rulings quickly.

11:30:29 7 But I have to see it in context to be able to rule
8 on the objection. Getting it in a chart doesn't help me.
9 I've just got to then go try to pick out pages and lines and
10 figure out what is relevant to the objection.

11:30:43 11 MS. KOWALZYK: Yeah, we understand. And we've had
12 cases where it's been done both ways, and our understanding
13 was we were not to do that in this case. So I apologize.

14 THE COURT: Well, it may have been our
15 miscommunication to you. Okay.

16 MR. LOPEZ: You made mention that you wanted the full
17 transcript. There's another way to --

18 THE COURT: I don't want the full transcript.

11:30:51 19 MR. LOPEZ: There's a way to simplify this. The
20 people that do the videos and do the cuts on the videos, they
21 can actually create a report that has just -- in color, so
22 you'll know what plaintiffs' assertions are and you'll know
23 what the defendants' counters might be, where you can --
24 you'll just get that part of the transcript. It's a much
11:31:08 25 easier read, it's much easier to deal with, and -- but you

11:31:11 1 mentioned that you wanted maybe more of that to get context.

2 But I think --

3 THE COURT: If I've got a transcript in front of me,
4 I'm not going to read any words that aren't highlighted.

11:31:22 5 MR. LOPEZ: Okay.

6 THE COURT: If yours are yellow and yours are blue,
7 that's what I'm going to read, I'm going to read the objection
8 and rule. So I don't need the whole transcript.

9 MR. LOPEZ: What I'm telling you is that we can give
11:31:32 10 you a 350-page transcript in about 20 pages, because it's just
11 going to have in color what the plaintiffs have designated --

12 THE COURT: That's great.

13 MR. LOPEZ: Okay. That's what we'll do.

14 THE COURT: That's much more helpful. Okay.

11:31:44 15 A second issue that's raised on pages 47 and 48 is
16 what we do with live witnesses. I will tell you my
17 preference always has been that if we're bothering somebody
18 to come to the courthouse or to come to Arizona to testify,
19 we ought to give them the courtesy of putting them on once
11:32:02 20 through all questioning, and not have them have to come back
21 during somebody else's case.

22 So my inclination would be if the plaintiff calls a
23 Bard witness, we do all of the questioning of that witness
24 while they're here in the courtroom and they don't have to
11:32:17 25 come back again.

11:32:17 1 And I can at the outset explain to the jury that
2 we're going to spend a little more time with this witness so
3 they don't have to come back during Bard's case.

4 Do you all have a problem with our doing that?

11:32:31 5 MR. NORTH: Your Honor, we do not. In fact, we think
6 that would work better and would be certainly more convenient
7 for our witnesses, with maybe one exception or two exceptions.
8 There are a couple of witnesses that we may want to reserve
9 our direct until after we've heard --

11:32:45 10 THE COURT: I'm not saying you have to do it this
11 way.

12 MR. NORTH: Okay. Then that's fine.

13 THE COURT: I'm saying if we -- for strategic reasons
14 you think they need to be called twice, you can impose that on
15 them. But if there isn't a strategic reason, I'd rather get
16 the witness on and off once.

17 MR. NORTH: Okay. Thank you, Your Honor.

18 MR. LOPEZ: Well, I would like to know who that is
19 going to be. In other words, I don't know whether to say I
20 object or not object or I -- I want to propose something
21 different to you if it's going to depend on the witness. A
22 couple of these witnesses, if he puts his direct on it, it's
23 going to be three hours of the defense case in the middle of
24 our case, and I think I would have a problem with that.

21:33:24 25 That's probably the exception. Some of these are

11:33:26 1 just maybe five or six more questions or ten more minutes of
2 him putting on his case. That's not a problem. But all of a
3 sudden, in the middle of the plaintiffs' case, we've got to
4 hear the direct examination? I think I would have a problem
11:33:39 5 with that, Your Honor. If they can just tell me who it is
6 they intend to allow us to put on --

7 THE COURT: Let's have you both confer about that and
8 figure that out. If there's a problem, I'll be happy to
9 address it.

11:33:50 10 MR. LOPEZ: Okay.

11 THE COURT: I'm thinking about the convenience of the
12 witnesses. That's what I'll like to preserve.

13 All right. On page 48 --

14 MR. LOPEZ: Your Honor, let me say this, too. It
11:34:01 15 might be a good idea -- time to bring this up: We don't have
16 a who they're going to call list. It's all may call. And
17 their suggestion they're going to wait until we put our case
18 on for them to make that determination, like they've never
19 seen this case before. They know what we're doing. I mean,
11:34:19 20 we actually showed them this entire case about six months ago.

21 THE COURT: That's easy. That's easy. You should
22 tell them everybody you now know you're going to call.

23 MR. NORTH: Okay.

24 THE COURT: And I recognize there may be some you
11:34:31 25 don't know yet. But everybody you know you're going to call,

11:34:33 1 tell them.

2 And incidentally, while we're on this point, I
3 wholeheartedly agree with the notion that you give each other
4 48 hours notice on who the witnesses are. And I know that
11:34:42 5 can sometimes change, but on Tuesday you should be
6 advising -- the close of Tuesday, you should be telling each
7 other who you're intending to call on Thursday so there's
8 time for people to prepare their cross-examination.

9 On Friday, you should be telling -- on Thursday,
11:34:57 10 telling them who you intend to call on Monday, and on Friday
11 who you intend to call on Tuesday.

12 Now, again, there will be some variations that
13 occur, but, in fairness, people ought to be able to know who
14 they should be preparing for.

11:35:12 15 MR. LOPEZ: Well, we wish it wasn't that, but let me
16 ask you for a compromise on the Thursday/Monday. I mean,
17 Saturdays are Wednesdays to people when they're in trial. I
18 mean, why can't that also be a 48-hour issue? We may not even
19 decide until Saturday.

11:35:31 20 THE COURT: If you want to tell them on Saturday
21 and -- if you're not going to maintain radio silence over the
22 weekend, then we can just apply the 48-hour rule all the way
23 through.

24 MR. LOPEZ: If you would do that --

11:35:44 25 THE COURT: So if you're going to call somebody on

11:35:45 1 Tuesday, at the latest you tell them on Sunday.

2 MR. LOPEZ: Okay.

3 MR. NORTH: All right.

4 THE COURT: So we'll just make it a 48-hour rule.

11:35:53 5 Okay. On page 48, defendants object to
6 Dr. Kandarpa, K-A-N-D-A-R-P-A, saying he was never identified
7 as a fact witness.

8 What's the response from plaintiffs on that?

9 MR. LOPEZ: Well, we did file a supplemental -- we
11:36:11 10 almost didn't, but I figured in abundance of caution we would.
11 I mean, he's a witness that is well-known to the defense. His
12 documents, his presence, have been pretty -- I mean, pretty
13 visible in cross-examination of experts. Dr. Kessler, his
14 documents have come in through depositions of our experts,
11:36:35 15 their experts.

16 THE COURT: Let me interrupt you, Mr. Lopez. What I
17 didn't understand was what you said at the beginning. Did you
18 disclose him?

19 MR. LOPEZ: We didn't disclose him because we weren't
11:36:44 20 really -- at the time, weren't fully aware of his
21 significance. Don't forget, this was done in August.

22 THE COURT: Okay. That's fine. Let me ask a couple
23 of other questions. Was he deposed?

24 MR. LOPEZ: He was not deposed.

11:36:57 25 THE COURT: All right.

11:36:58 1 MR. LOPEZ: But all of his documents are -- I mean,
2 he's basically a witness who's going to testify about
3 documents that we've received. They're not signed. There's
4 e-mails that involve him that he's going to be able to testify
11:37:10 5 to. And someone that's well-known.

6 Frankly, if you look at some of the testimony that
7 they -- where they talk about who were the doctors involved
8 in the Everest study, they never mention him. In other
9 words, it was just happenstance that we found his name in a
11:37:29 10 document.

11 THE COURT: I'm -- I'm just trying to save us some
12 time, Mr. Lopez. Let me cut to what I think is the heart of
13 this issue.

14 If he was not disclosed, either in response to
11:37:38 15 discovery or under Rule 26(a) disclosure --

16 MR. LOPEZ: Not in a formal way, but he was -- we
17 filed a supplemental --

18 THE COURT: Let me finish.

19 -- then the test for whether or not I exclude him is
11:37:47 20 in Rule 37(c)(1), and that says if he wasn't disclosed, he
21 should be excluded, unless the failure to disclose him was
22 substantially justified or harmless.

23 I think what I hear you arguing is it's harmless
24 because you think the defendants knew all about him and so
11:38:05 25 they're not prejudiced by the fact that you now want to call

11:38:07 1 him. Is that your argument?

2 MR. LOPEZ: Yes, Your Honor. They were documents
3 that were produced late. When I say "late," I don't mean
4 beyond the discovery, but there were documents that came in in
11:38:19 5 a production that was very late in the production, and that he
6 was revealed in -- I think it was in our preemption brief,
7 depositions of experts, reliance from experts, disclosed --
8 they were disclosed -- he was disclosed in our state court
9 disclosures in Arizona. So it's not like this is a surprise
11:38:43 10 witness who has facts. They know what the facts are that
11 he's -- would testify to.

12 THE COURT: Okay. I understand that point.

13 What's the defense response?

14 MR. NORTH: Your Honor, we do agree, of course. We
11:39:04 15 knew who Dr. Kandarpa was, just as we know who the dozens of
16 doctors are that worked on clinical studies or had involvement
17 in the development of the Bard products.

18 I believe the Court said there were two prongs to
19 that test. Is it substantially justified --

11:39:21 20 THE COURT: Substantially justified or harmless, is
21 what Rule 37(c)(1) identifies.

22 MR. NORTH: We would submit it is not substantially
23 justified that they did not disclose this person earlier as a
24 potential witness. He was first mentioned by them, I believe,
11:39:37 25 in September of 2016 in a deposition of one of our employees.

11:39:45 1 He's been talked about by their expert witnesses before they
2 ever answered the interrogatories, where they failed to
3 disclose them. He's been known to them for some time.

4 On July 28, they answered our case specific -- or
11:40:01 5 our interrogatories in the *Booker* case, and those
6 interrogatories asked them to identify each individual with
7 knowledge about claims that plaintiff may use to support her
8 claims. They listed over 90 people. Bard employees, former
9 employees, consultants, physicians. They never listed
11:40:21 10 Dr. Kandarpa.

11 They supplemented their responses in August 15 of
12 1917, did not list Dr. Kandarpa. They first indicated to us
13 their intention to call him as a witness when they gave us
14 their version of the Pretrial Order just this last Sunday,
11:40:38 15 and they only supplemented their interrogatory responses
16 Wednesday evening, after the Pretrial Order was filed.

17 Your Honor, it is not harmless. We don't know what
18 this doctor is going to say. He doesn't work for Bard. Bard
19 has -- as far as I know, has had no involvement with him
11:40:55 20 since the Everest study ten years ago.

21 We would have deposed him if they had indicated to
22 us earlier that they were going to potentially call him as a
23 witness. Well, they said, well, you knew about him. Well,
24 we knew about dozens of doctors. In the course of this MDL,
11:41:13 25 we've been doing discovery, both sides, on over 15 years of

11:41:18 1 development, of more than six generations of filters. If we
2 went and deposed every doctor we knew about that had some
3 role at some point, discovery would be finishing in 2020 in
4 this litigation. I'm sure the Court would not allow that,
11:41:36 5 but theoretically.

6 It is not harmless because we did not have the
7 opportunity because we had no prior notice they were going to
8 call this doctor as opposed to many others that had been
9 listed, and we just -- it would never have been feasible or
11:41:52 10 realistic or proportional to go and depose every doctor that
11 had involvement in any of our developmental efforts over 15
12 years.

13 So we don't think it is harmless and don't think it
14 is fair for them to do this at this late time, and we also
11:42:08 15 don't think it is substantially justified because they have
16 known about this doctor for months. Long before they even
17 answered our interrogatories.

18 THE COURT: Okay. Thank you. I understand that.

19 Anything more, Mr. Lopez, on that issue?

11:42:23 20 MR. LOPEZ: I think I may have mentioned this. I
21 think one of the things that -- we were kind of misled about
22 the significance of Dr. Kandarpa, because every time we would
23 ask questions of witnesses about who was involved in the
24 Everest trial, we were always given the names Dr. Venbrux and
11:42:46 25 Dr. Kaufman. It wasn't until these documents -- again, his

11:42:48 1 documents are significant. And the issue is I don't know what
2 kind of objections they're going to make to the documents, I
3 don't know whether or not they're going to allow -- because
4 they were produced by a third party through Bard. But it's
11:43:02 5 certainly -- I mean, it should be harmless to them. I mean,
6 they've known about the significance of this witness's
7 minutes, meeting minutes and the documents we've used at
8 depositions and in expert reports.

9 THE COURT: When did you get the documents?

11:43:23 10 MR. LOPEZ: You know, I can just tell you that we
11 just discovered them -- they may have been in our database,
12 but the first time we saw these documents was shortly before
13 Dr. Kessler's deposition. I think that was in the preemption
14 case.

11:43:39 15 Julia, when was that deposition? I can't remember.

16 MS. REED ZAIC: Summer of last year.

17 MR. LOPEZ: The summer of last year.

18 THE COURT: Okay. Thank you.

19 I'm not going to allow Dr. Kandarpa to testify.

11:43:52 20 Rule 37(c) is very clear. C(1). It says: If a party fails
21 to provide information or identify a witness as required by
22 Rule 26(a) or (e), the party is not allowed to use that
23 information or witness to supply evidence on a motion, at a
24 hearing, or at a trial unless the failure was substantially
11:44:12 25 justified or is harmless.

11:44:14 1 I don't think the failure to disclose Dr. Kandarpa
2 is substantially justified. It's been evident that he's been
3 known about by the plaintiffs for months and has been
4 addressed in depositions. And I don't believe it's harmless.
11:44:28 5 I believe depositing a witness in this case has been an
6 important step throughout the case. It appears that
7 defendants have sought to depose every witness that was
8 identified. Dr. Kandarpa wasn't identified as a witness and
9 therefore was not deposed, and therefore I do not believe the
11:44:46 10 failure to disclose him was harmless. And therefore my
11 conclusion is that he cannot testify under Rule 37(c)(1).

12 MR. LOPEZ: Two things, Your Honor: Number one, what
13 if he is -- we could make him available for a deposition,
14 number one? Number two is the documents that are purportedly
11:45:08 15 authored by him, if we have -- if there's an issue on
16 foundation or authenticity, could we at least have him testify
17 to authenticate the documents?

18 THE COURT: On the first issue, no. Discovery is
19 closed. We're not going to have him deposed.

11:45:23 20 On the second issue, if there is a Kandarpa document
21 that's been talked about by other witnesses that you can get
22 into evidence on that basis, then you can seek to get it into
23 evidence on that basis. But I'm not going to allow him to
24 testify at trial. So if you need him to authenticate a
11:45:41 25 document, he's not available for that purpose. I think Rule

11:45:44 1 37(c)(1) is very clear, and that's my conclusion on
2 Dr. Kandarpa.

3 MR. LOPEZ: What if we had his authentication of
4 those documents outside the presence of the jury, just to lay
11:45:55 5 the foundation? They were produced by Bard. I don't know
6 whether they're going to object to them. They're pretty
7 significant documents.

8 THE COURT: I understand what you're saying,
9 Mr. Lopez. All of this points up to me the fact that you knew
11:46:07 10 he should be a witness long ago if you wanted to use the
11 documents. He wasn't identified, he wasn't deposed. I'm
12 going to enforce Rule 37(c)(1).

13 MR. LOPEZ: Okay. We'll have to use him in the next
14 trial, Judge.

11:46:21 15 THE COURT: All right.
16 The issue is paragraph -- or the next issue is on
17 page 48, paragraph 3. Dr. Thomas Kinney as a fact witness.
18 And I think the argument is that the plaintiffs have
19 designated him as a fact witness.

11:46:37 20 Is that true, Mr. Lopez?
21 MR. LOPEZ: I'm sorry, Your Honor, did we designate
22 him as a fact witness?

23 THE COURT: Dr. Kinney.

24 MR. LOPEZ: I think we did.

11:46:47 25 THE COURT: And if so, how is he --

11:46:50 1 MR. LOPEZ: Pardon me?

2 THE COURT: How is he a fact witness?

3 MR. LOPEZ: He's a fact witness because of his -- not
4 when he was doing work for Bard, but he's a fact witness on
11:46:58 5 his -- some of the interactions, communications he may have
6 had with Bard sales reps, Bard personnel outside of the scope
7 of his doing work for Bard.

8 THE COURT: Okay. So you are not intending, when you
9 designate him as a fact witness, to have him talk about his
11:47:13 10 prior work for Bard?

11 MR. LOPEZ: No. I understand your ruling on that.
12 it's not going to be about his prior work.

13 There is one incident where he was at a meeting with
14 others, other physicians, where he wasn't doing work for
11:47:26 15 Bard, because we -- the circumstances of that meeting, what
16 grew out of that meeting, that's been produced as a document,
17 a summary of the meeting. Some of the other doctors have
18 been deposed on that. I don't think that's doing work for
19 Bard. That's him being called in with a bunch of other
11:47:45 20 physicians who have been deposed on that issue, and a
21 document that's not been protected.

22 THE COURT: Okay.

23 All right. Mr. North, or whoever on the defense
24 wishes to speak, if he's not being called as a fact witness
11:47:58 25 to testify about his work for Bard, do you have a basis for

11:48:00 1 objecting to him testifying as a fact witness?

2 MR. NORTH: Well, I have to see what he says. I
3 mean, I don't know that I could say that now. There may be
4 objections to specific questions. He just sounded -- their
11:48:15 5 description of him as a fact witness stated plaintiff expects
6 that he is knowledgeable regarding the matters that were the
7 subject of his relationship with Bard, which sounded to us
8 what the Court had excluded.

9 THE COURT: Okay. I think we've clarified that here.
11:48:28 10 He's not going to be called to testify about his relationship
11 with Bard, and we'll hear objections on whether there is
12 something else in the fact testimony that you think is
13 improper, but I'm not going to exclude him as a fact witness.

14 All right. We've already talked about paragraph 4
11:48:51 15 on page 48 which is the 48 hours notice.

16 My next question for you all was page 61, where you
17 made reference on line 20, 21 to the disclosure of
18 impeachment exhibits. Do you -- have you all talked about
19 and reached some agreement on what can or cannot be an
11:49:18 20 impeachment exhibit?

21 MS. REED ZAIC: Your Honor, I think the agreement was
22 that in your guidelines, the wording is "unless other
23 arrangements are made." And we have agreed that we would like
24 to make other arrangements. I believe --

11:49:28 25 Kate, tell me if I'm wrong.

11:49:29 1 -- I think we discussed 24 hours in advance of use
2 as opposed to all of them 48 hours before trial, leaving
3 intact the Court's requirement of them being provided in a
4 sealed envelope.

11:49:43 5 MS. HELM: That's correct, Your Honor.

6 THE COURT: Okay. And do both sides intend to mark
7 or to provide impeachment exhibits in envelopes?

8 MS. REED ZAIC: Yes, we would comply with that part
9 of the order. It is just the 48 hours before trial I believe
11:49:56 10 both sides wanted to change.

11 THE COURT: Let me just flag an issue that comes up
12 sometimes on impeachment exhibits so you can think about it.
13 There is a question, and it's I think still a subject of a
14 division in the courts, as to what is meant by "solely for
11:50:11 15 impeachment," as you may know.

16 There are some courts which view solely for
17 impeachment as referring to the use of the document. So if
18 it is going to be used solely for impeachment, then it can be
19 put in a sealed envelope and not shown.

20 There are other courts which interpret solely for
21 impeachment to mean that the only relevancy of the document
22 is solely for impeachment. And if the document has relevancy
23 to any other issue in the case, then it's not solely for
24 impeachment and can't be withheld and put in a sealed
11:50:43 25 envelope, it has to be disclosed.

11:50:47 1 I have in the past concluded that the second
2 interpretation is the better reading of the rule, so that an
3 impeachment document is a document that's not relevant to the
4 general issues in the case, its relevancy is that it
11:51:01 5 impeaches a witness. I don't know if that creates concerns
6 for any of you about what your plans are with impeachment,
7 but that's the approach I've taken.

8 All right. I see heads --

9 MS. REED ZAIC: Good rule.

11:51:13 10 MS. HELM: We agree, Your Honor.

11 THE COURT: Okay. All right. That's what I wanted
12 to make sure you understood.

13 MR. LERNER: Your Honor, one question as well, for
14 the impeachment thing. Since we are running each other notice
11:51:27 15 48 hours of witnesses, how are we going to provide 48 hours
16 notice of impeachment evidence if we don't know who the
17 witnesses --

18 THE COURT: It's not a matter of giving notice. All
19 you do is say it's in an envelope. It may or may not be used
11:51:41 20 during the witness's testimony. So you are not giving that to
21 other side to see.

22 MR. LERNER: Right. I'm saying providing the Court
23 that envelope 48 hours beforehand when we don't know who the
24 witness is --

11:51:52 25 THE COURT: Oh, I see what you mean.

11:51:54 1 MS. HELM: 24. 24 hours notice.

2 THE COURT: 24. Yeah, it's shorter.

3 MR. LERNER: Okay.

4 THE COURT: I wanted to talk about paragraph A on
11:52:01 5 page 62 and this issue of sealing exhibits. Here's what I was
6 unsure about: The fact that exhibits are given to Traci and
7 admitted into evidence does nothing to make them public. They
8 don't go into the Court's docket. They're evidence for
9 purposes of the trial, but they stay in the courtroom in their
11:52:20 10 box. They go on the software to be shown to the jury. They
11 never get into the district court docket. Where they
12 eventually get into the record that might be public is when
13 they go to the Court of Appeals if they're attached to a brief
14 or something.

11:52:34 15 And so I didn't understand what the concern was on
16 page 62 from the defendants about us possibly making them
17 available to the public during trial.

18 MS. HELM: Your Honor, may I address that?

19 THE COURT: Yeah.

11:52:52 20 MS. HELM: Frankly, the concern is that we have to
21 raise the issue of confidentiality to make sure that we
22 preserve it and we don't waive it. And so the purpose of this
23 paragraph, maybe not so artfully written, was to preserve our
24 right to move to seal exhibits and/or portions of the
11:53:11 25 transcript after the trial, and not knowing what the Court did

11:53:17 1 with them. We wanted to make sure that we weren't in some way
2 waiving that by asking to address it at the conclusion of the
3 trial and asking that it be maintained confidentially during
4 the trial.

11:53:26 5 THE COURT: Okay. That issue's preserved. You have
6 not waived it.

7 MS. HELM: Thank you.

8 THE COURT: So if you decide we need to address it
9 later, we can do that.

11:53:33 10 MS. HELM: Thank you, Your Honor.

11 THE COURT: Page 67. You mention -- well, let me
12 look. You mention on line 11, 12 that you all are talking
13 about developing stipulated summaries of background
14 information for witnesses, which is great. That will save
11:54:10 15 time.

16 How did you want to present that information to the
17 jury?

18 MR. LOPEZ: Well, my thought was right before we play
19 the video, whoever is offering the video can stand up and read
11:54:21 20 it to the jury.

21 THE COURT: Is that agreeable?

22 MS. HELM: Yes, Your Honor.

23 THE COURT: Okay. That's fine. We'll plan to do it
24 that way.

11:54:37 25 Okay. Page 68 has some trial hours. When I add

11:54:45 1 them up, and I've added them up four times, the plaintiffs
2 come to 30 hours. I've allotted you 27.

3 MR. LOPEZ: We were counting those extra 20 minutes
4 here and there, Judge.

11:54:59 5 THE COURT: I just want to make sure you understood
6 my order said 27.

7 MR. LOPEZ: It is. But we kind of added up the 20
8 minutes you were talking about here and maybe 15 there.

9 THE COURT: Okay. We'll call these aspirational
11:55:12 10 numbers.

11 MR. LOPEZ: Aspirational numbers.

12 THE COURT: We'll see what we can do.

13 MR. NORTH: Your Honor, I did want to note that he
14 tried to claim all those extra 20-minute increments for
11:55:20 15 himself, that if those are going to be given out, we'd like a
16 few, too.

17 MR. LOPEZ: Judge, I think Mr. North is only going to
18 use like 20 of his anyway, Judge, so might be some left over.

19 THE COURT: All right. And we will do our best to
11:55:35 20 provide the time needed.

21 I'll tell you something, though, that I concluded
22 yesterday as I looked at the calendar. As I told you before,
23 I'm supposed to leave town Monday morning, April 2nd, to get
24 to some meetings. And under our current schedule, the jury
11:55:54 25 would -- if we used all these hours, the jury would not get

11:55:56 1 the case until noon on Friday. I think there's a good chance
2 they'll need more than a half day to deliberate.

3 So what I think I'm going to do is take one of those
4 Mondays, either the 19th or the 26th, and I'm going to move
11:56:13 5 all those sentencing that I told you about before to mid
6 April so that we can take that day for trial. And that
7 doesn't give us more time, but what -- because the reason I
8 want to do it is to get the case to the jury at noon on
9 Thursday so they've got a day and a half to deliberate. Now,
11:56:30 10 if they're still deliberating Friday night, I'll call into my
11 meeting, which I shouldn't do, but I'll do it. I'll be here
12 Monday morning if I need to.

13 But I think if we get it to the jury by Thursday at
14 noon, there's a decent chance they'll have enough time for a
11:56:47 15 verdict by Friday at the close of business.

16 Does it matter to you whether the day we take is
17 Monday the 19th or Monday the 26th?

18 MR. LOPEZ: Well, it does for us, because I think the
19 19th is in the middle of our case, and we've scheduled a lot
11:57:02 20 of people for that Tuesday through Friday already, Your Honor.
21 Might have a problem.

22 THE COURT: Moving them?

23 MR. LOPEZ: Yeah.

24 THE COURT: Okay. That's fine.

11:57:12 25 So we'll take the hearings on the 26th, Traci, and

11:57:16 1 move those to April.

2 So that means we will be in trial on Monday the
3 26th. And that will give us a day and a half for jury
4 deliberations.

11:57:38 5 I might not have been reading it carefully enough,
6 but when I looked at your 174-page exhibit list, I couldn't
7 tell whose exhibits were whose. Whose are defendants and
8 whose are plaintiffs? The chart doesn't say.

9 MR. LERNER: The first 5,000 are the plaintiffs, and
11:58:08 10 starting at number 5,000 are defendants.

11 THE COURT: Okay. That's what I couldn't tell. I
12 saw that there was a break at 5,000.

13 Okay.

14 All right. I am going to adopt the Final Pretrial
11:58:38 15 Order, and so it will be the Final Pretrial Order for trial
16 for purposes of Rule 16(e). The significance of that, as you
17 know, is once the Court adopts the Final Pretrial Order, it
18 can only be changed to prevent manifest injustice, the
19 highest standard in the civil rules. So witnesses, exhibits,
11:58:58 20 objections not identified can only be added to prevent
21 manifest injustice.

22 MS. REED ZAIC: Just before you enter that order, if
23 I could make a clarification on page 33, Your Honor.

24 THE COURT: Yes.

11:59:12 25 MS. REED ZAIC: Deals with a witness David Dimmit.

11:59:15 1 THE COURT: Uh-huh.

2 MS. REED ZAIC: If you recall, you allowed plaintiffs
3 to take a supplemental deposition with regard to a potential
4 punitive phase. We didn't have the name of the witness, or
11:59:24 5 they passed like ships in the night as we were submitting
6 this, and he or she was identified to us, so we left a place
7 holder, and the name of that witness, who is being deposed
8 today, actually, is Mehdi, M-E-H-D-I, Syed, S-Y-E-D.

9 THE COURT: Is that in place of David Dimmit?

11:59:45 10 MS. REED ZAIC: That is who was identified for the
11 supplemental deposition.

12 THE COURT: So what is --

13 MS. REED ZAIC: So we have testimony from Mr. Dimmit,
14 and you allowed a supplemental deposition with respect with
11:59:55 15 regard to net worth --

16 THE COURT: That's the two-hour one; correct?

17 MS. REED ZAIC: Exactly.

18 THE COURT: And what is the witness's name?

19 MS. REED ZAIC: The witness's name is Mehdi Syed,
12:00:02 20 M-E-H-D-I, S-Y-E-D.

21 MS. HELM: Your Honor, if I may, he's listed on
22 page 58 in the Pretrial Order in defendants' witnesses.

23 THE COURT: All right. So with the clarification
24 that that's also being added to the plaintiffs' list, I will
12:00:21 25 adopt the Final Pretrial Order.

12:00:23 1 I'm not going to actually sign a version and enter
2 it as the order. I'm simply going to note in the minute
3 entry that it's -- or in the order that comes out after this
4 that I've adopted it.

12:00:33 5 All right. We are at the noon hour. I will tell
6 you the issues I wanted to talk about after lunch are the
7 challenges for cause, and also I think we ought to talk about
8 caudal versus cephalad migration. That is an issue
9 identified in one of my orders.

12:00:57 10 And a few other trial procedures that I'll review
11 with you.

12 So why don't we break until 1 o'clock. If you could
13 have your individual ready to go at 1:00, plaintiffs, on the
14 challenges for cause, we'll plan to take that up right at
12:01:14 15 1 o'clock. Hopefully our conference line will be clearer and
16 we won't have the static.

17 MR. LOPEZ: Mr. Wenner is going to make a liar out of
18 me. He told me he was going to be out of town today, but I
19 guess he isn't now.

12:01:26 20 THE COURT: Oh, so he's going to be here?

21 MS. REED ZAIC: He's on his way.

22 MR. LOPEZ: He will be here.

23 THE COURT: Okay. That's good.

24 MR. LOPEZ: I didn't misrepresent that. It was my
12:01:32 25 best knowledge.

12:01:33 1 THE COURT: That's fine.

2 Okay. We'll see you at 1 o'clock. Thank you.

3 (Recess taken from 12:02 to 1:00. Proceedings resumed in
4 open court.)

13:00:40 5 THE COURT: Thank you. Please be seated.

6 All right. Counsel, what I'd like to do now is the
7 challenges for cause based on the jury questionnaire. And I
8 think what we ought to do is have the party making the
9 challenge identify the juror, give a one-sentence explanation
10 for it, and point out where in the questionnaire that fact
11 is. Then hear if the other side agrees or disagrees. And if
12 you both agree, then I'll look at the questionnaire and
13 decide if I agree, and we won't have to have more argument.
14 If the other side disagrees, then we can have more discussion
15 about precisely what is the basis for the challenge for
16 cause.

17 So why don't we start with defendants and have you
18 identify those you think should be challenged for cause.

19 MR. NORTH: Thank you, Your Honor. We start with
20 Number 31. On question 60, he says he can be fair, but he
21 also discusses that his niece has a lawsuit against an
22 artificial hip manufacturer.

23 THE COURT: This is Juror 31?

24 MR. NORTH: Yes, Your Honor.

13:02:52 25 THE COURT: And what question did you say that is?

13:02:58 1 MR. NORTH: Yes, question 60.

2 I'm sorry; he says he cannot be fair.

3 THE COURT: What's the response from plaintiffs' 4
counsel?

13:03:39 5 MR. LOPEZ: Your Honor, we we're going to have
6 Mr. David Wenner respond for the plaintiffs.

7 MR. WENNER: Your Honor, I apologize for my dress. I
8 wasn't prepared. I beg the Court's forgiveness. I generally
9 don't dress like this when I appear in court.

13:03:53 10 THE COURT: I've got a tie I could loan you.

11 MR. WENNER: If you want me to put it on, I will.
12 More than happy to.

13 THE COURT: That's all right.

14 MR. WENNER: I don't have a -- I agree, Your Honor.
15 They can -- they can remove for cause.

16 THE COURT: I agree in light of the fact that he said
17 he could not be fair and he's got a medical products case in
18 his family pending.

19 I'm going to grant the challenge for cause to
13:04:16 20 Juror 31.

21 MR. NORTH: The next one, Your Honor, is Number 78.

22 Again, looking to question 60 on page 12, she says
23 that she cannot be fair, and she has a really tragic case
24 that led to that response. Her husband had a very adverse
13:04:43 25 reaction for five years to a pharmaceutical, and when he came

13:04:48 1 out of that, they divorced out of -- after 49 years of
2 marriage, and she blamed it on the pharmaceutical.

3 THE COURT: All right. Plaintiffs' response.

4 MR. WENNER: Your Honor, to me this is a little bit
13:05:03 5 more attenuated than the last one. I think that I'd like the
6 opportunity -- plaintiffs to have the opportunity to follow up
7 in voir dire, because I don't really see the relationship
8 of -- between Lipitor and a marriage relationship and the
9 quality of marriage. So maybe she doesn't understand the
13:05:22 10 question. So I would object on the cause analysis for that.

11 THE COURT: Mr. North, did you want to add anything
12 else?

13 MR. NORTH: Yes, Your Honor. If you also look at
14 question number 51, she explains the situation in pretty
13:05:37 15 graphic detail.

16 THE COURT: All right. Let me look at that.

17 MR. WENNER: Your Honor, I agree she could be struck
18 for cause.

19 THE COURT: I think reading question 51 in connection
13:06:06 20 with question 60 makes it clear she's had a traumatic event
21 related to a medical product, so I'm going to grant the
22 challenge for cause to Juror 78.

23 MR. NORTH: Your Honor, the next one would be
24 Number 84.

13:06:34 25 And if you look at the last page, page 12, she says

13:06:38 1 there's no reason she cannot be fair in response to question
2 number 60, but then in the space for additional responses she
3 gives a lengthy description about her cousin, who she
4 believes has some type of filter in her carotid artery. I'm
13:06:54 5 not sure what kind of device it is, but she certainly
6 believes it is akin to our filter, and she believes that
7 filter caused a stroke in her cousin, and is very conflicted
8 about that.

9 THE COURT: All right, let me read this.

13:08:27 10 All right. Plaintiffs' comment.

11 MR. WENNER: Your Honor, I would object for exclusion
12 on cause because in the last paragraph she points out that
13 every case is different, and she also says she would try to be
14 impartial, but she wanted to disclose this fact to be honest.
13:08:47 15 So I think we ought to have the opportunity to voir dire her.
16 I'm concerned that -- I'd like to talk to her -- like the
17 plaintiffs to talk to her about, you know, her mother's
18 declining health and whether she would be able to stay present
19 and focused on the evidence, listen to the evidence.

13:09:03 20 THE COURT: All right. I am not going to grant the
21 challenge for cause to Juror 84. She does indicate she
22 believes she could try to be fair. I think follow-up
23 questioning would be appropriate.

24 MR. NORTH: Next one would be Number 94, Your Honor.
13:09:18 25 And, again, in question number 60, page 12, he says he cannot

13:09:23 1 be fair because two members of his family have had adverse
2 experiences with ports. Port devices manufactured by Bard.

3 THE COURT: Comments from plaintiffs.

4 MR. NORTH: Similar comment in response to question
13:09:52 5 number 1 on the first page.

6 MR. WENNER: Your Honor, no objection.

7 THE COURT: You can actually stay seated, both of
8 you. That way you're talking more directly into the mic.

9 MR. WENNER: Thank you.

13:10:12 10 THE COURT: I'm going to grant the challenge for
11 cause to Juror Number 94. It seems clear this juror is
12 indicating that he does not believe he could be fair based on
13 family experiences with Bard products.

14 MR. NORTH: Next, Your Honor, Number 106. In
13:10:31 15 response to question 60, again on page 12, this juror says she
16 cannot be fair because of past complications she has had with
17 an IVC filter.

18 MR. WENNER: No objection, Your Honor.

19 THE COURT: All right. I agree. In paragraph 49,
13:11:03 20 she indicates that she's had an IVC filter, that it protruded
21 through her vena cava. She does not think she could be fair.
22 That's very close to the facts of this case, so I will grant
23 the challenge for cause to Juror Number 106.

24 MR. NORTH: 113.

13:11:26 25 You -- I must say your filing system is more

13:11:30 1 workable than mine, I think, with this.

2 Number 113, on question 60 again, page 12, she says
3 she cannot be fair because of her mother's medical condition.
4 She then explains in other responses the problems. She says
13:11:56 5 in question 40 that she believes the medical profession is
6 dishonest. She clearly blames the pharmaceutical company for
7 her mother's condition. That is question number 36.

8 THE COURT: Plaintiffs' response.

9 MR. WENNER: No objection, Your Honor.

13:12:26 10 THE COURT: I'm going to grant the challenge for
11 cause to Juror 113. In addition to her mother's experience,
12 she also indicates elsewhere that she's super sensitive and
13 emotional, doesn't think the medical profession is honest, she
14 doesn't respect people who file lawsuits. I'm not sure she
13:12:52 15 could be fair and objective, so I will grant that challenge
16 for cause.

17 MR. NORTH: Number 125, Your Honor.

18 THE COURT: This is an e-mail; right?

19 MR. NORTH: Yes.

13:13:07 20 THE COURT: Okay.

21 MR. NORTH: The juror lists in response to number 60
22 that he knows no reason why he cannot be fair. But if you
23 look at the answers to number 37, he has had an enormous
24 amount of exposure to the press, the NBC reports regarding
13:13:28 25 Bard. He even references the alleged forgery on the FDA

13:13:32 1 application. In 38, he says that he's read a lot of articles
2 about Bard's failure to warn patients and physicians of the
3 increased risks. 40, he says, "Most of the articles I've read
4 have not portrayed C.R. Bard in a positive manner." And
13:13:51 5 number 50, he says his next-door neighbor has severe
6 complications due to an IVC filter.

7 THE COURT: All right. Plaintiffs' response.

8 MR. WENNER: Your Honor, the juror, Mr. Lxxxxx, Juror
9 Number 125, said at the bottom he could be fair. And if we
13:14:10 10 exclude everybody that saw the NBC report, then we probably
11 would be excluding a lot of people. A number of people saw
12 that. I don't think that is a basis for exclusion.

13 Now, it may well be that after voir dire that it
14 turns out the juror should be excluded for cause, but I'd at
13:14:24 15 least like the opportunity to test those attitudes to
16 determine whether or not in fact the person really is a cause
17 challenge.

18 THE COURT: I'm not going to grant the challenge for
19 cause. This fellow clearly has been exposed to news reports.
13:15:08 20 But he also indicates in response to number 59 that he may
21 find it hard to side with the plaintiff because his mother has
22 been helped by a medical device. This may be somebody who can
23 be fair despite his previous exposure. So I think we should
24 ask him further questions.

13:15:26 25 MR. NORTH: Okay. The last one, Your Honor, would be

13:15:28 1 194. Okay. 194, in response to number 60, she says she
2 cannot be fair. She cites a defective hip implant suffered by
3 her mother. She believes it would cloud her thinking. In her
4 response to number 40, she talks more about the hip implant
13:16:01 5 and explains that she is skeptical of companies as a result.
6 And also in response to 51 and 52 she talks further about the
7 hip implant.

8 THE COURT: Plaintiffs' response.

9 MR. WENNER: Your Honor, she says she can't be fair,
13:16:27 10 I'm going to take her at her word and agree she should be
11 excused for cause.

12 THE COURT: I'm going to grant the challenge for
13 cause to Juror Number 194 for the same reason I did for
14 Juror 31.

13:16:38 15 Okay. Those are all of yours, Mr. North?

16 MR. NORTH: Yes, Your Honor.

17 THE COURT: Okay. How about from plaintiffs?

18 MR. WENNER: Your Honor, three challenges for cause,
19 beginning with Juror Number 135 and question 46. The question
13:16:58 20 says, "Do you have any strong feelings, positive or negative,
21 about people who file lawsuits?" And he says -- so this must
22 be a strong feeling -- he says, "I personally feel you should
23 always read the fine print and do research."

24 So it is obvious he has a prejudgetment in how a
13:17:16 25 patient should behave before an implant occurs. So before we

13:17:21 1 hear any evidence, this juror is already -- at least has a
2 judgment about informed consent and about what patient
3 behavior is, and I think that we start behind with this
4 juror, and this juror should be excluded for cause for those
13:17:39 5 reasons.

6 THE COURT: All right. Defense counsel.

7 MR. NORTH: Your Honor, he says unequivocally in
8 response to number 60 that he knows no reason why he cannot be
9 fair. And I think in light of that statement, his one comment
13:17:52 10 that was referenced is not sufficient for a cause challenge.

11 THE COURT: I am going to deny the challenge to
12 Juror 135. I do think the question 46 answer requires further
13 follow-up. It's not clear to me exactly what he means,
14 although it could be read as a negative comment on plaintiffs.
13:18:14 15 I think we need to ask questions about that. So I'm not going
16 to exclude him for cause at this time.

17 MR. WENNER: So the next one is Juror Number 136,
18 Your Honor. Question 54, he -- this juror indicated that he
19 thinks that the number of lawsuits filed in general have been
13:18:43 20 too high. Number 55, he thinks money damages from recent
21 lawsuits have generally been too high. And he supports
22 legislative reforms to place caps or limits on the amount of
23 money juries award. And he -- and then in number 57, if you
24 are chosen as a juror and you're not permitted to read or
13:19:10 25 listen to any media or internet coverage, he says, "I would

13:19:14 1 try, but my profession requires me to follow the news." And I
2 don't know if, you know, they're required not to do that.

3 I think based upon the totality of those answers to
4 the questions, I would move to strike Number 136 for cause.

13:19:35 5 THE COURT: Okay. Defense response.

6 MR. NORTH: Your Honor, first of all, in response to
7 number 60, this gentleman said there was no reason that he
8 knew of as to why he could not be fair. And furthermore, his
9 response about needing to follow the news, I think is a
13:19:53 10 perfectly fair response since his position is the director of
11 Maricopa County Department of Emergency Management. I think
12 we'd all appreciate him following the news.

13 THE COURT: Okay.

14 It appears to me that this juror has clearly
15 indicated that he favors one side. In paragraph -- pardon
16 me, question 35, he says he has an extremely negative view of
17 personal injury lawyers and one step down from an extremely
18 positive view of medical device manufacturers. Well, two
19 steps down. And an extremely positive view of corporations.

13:20:36 20 He says in response to question 46 that he is
21 generally suspicious of the motives of people who file
22 lawsuits and the attorneys who represent them. And then he
23 has the other answers, as well, that were pointed out by
24 plaintiffs counsel.

13:20:56 25 I'm going to grant the challenge for cause to

13:20:57 1 Juror 136.

2 MR. WENNER: Thank you, Your Honor.

3 The last challenge for cause is Juror Number 50 --
4 Number 150, excuse me.

13:21:20 5 MR. NORTH: What number?

6 MR. WENNER: Juror Number 150.

7 This juror -- you want to do it?

8 MR. NORTH: No, go ahead.

9 MR. LOPEZ: So this juror has said that he believes
13:21:40 10 that -- question number 54, that the number of lawsuits are
11 too high, that the damages are also too high, and he supports
12 legislative reforms to place caps on damages. And he also has
13 put number 1, extremely negative, on question 35 as to
14 personal injury lawyers, and he's neutral as to medical device
13:22:10 15 manufacturers and corporations, a number 4 on each of those.
16 So I would argue that he should be excluded for cause.

17 In addition, on number 37, he says he's heard there
18 have been lawsuits and settlement regarding IVC, so he's
19 obviously -- he has some preexisting knowledge about that.

13:22:31 20 But I would, based upon how he has responded in this
21 questionnaire -- and I will say, Your Honor, that simply that
22 when a juror says "I can't be fair" is different than when a
23 juror says, you know, "I can be fair." Because while "I
24 cannot be fair" is a conscious awareness of bias, the fact
13:22:50 25 that he says "I cannot be fair" doesn't mean that juror's not

13:22:53 1 actually biased. I just want to put that on the record.

2 THE COURT: Okay.

3 Defense response.

4 MR. NORTH: Your Honor, in response to number 60, he
13:23:01 5 does say there is no reason that he knows of as to why he
6 cannot be fair. He does not make any really perjorative
7 comments like the last juror did about tort reform and
8 lawsuits in general. He just says he believes the jury should
9 be able to limit the money award depending on the case. And
13:23:25 10 that is in response to number 56.

11 And as far as publicity goes, I mean, unlike the one
12 that we challenged that had very detailed knowledge, all he
13 says is, "I've heard of lawsuits."

14 THE COURT: I think this is a closer question than
13:23:42 15 Juror 136. I'm not going to grant the challenge for cause. I
16 think follow-up questions are warranted. But we should learn
17 more about those views.

18 Any others from plaintiffs?

19 MR. WENNER: No. No, sir.

13:23:55 20 THE COURT: Okay.

21 So I granted challenges for cause to Jurors 31, 78,
22 94, 106, 125, 194, and 136.

23 Is that right, Traci?

24 THE COURTROOM DEPUTY: I show 113.

13:24:12 25 THE COURT: Did I do it for 113 as well?

13:24:14 1 THE COURTROOM DEPUTY: Yes.

2 MS. HELM: Yes.

3 THE COURT: Yes. I did. Okay. And 113.

4 So we will exclude those jurors, plus all of the
13:24:31 5 folks that have been excused for hardship from the group of
6 jurors. We'll identify the 60 lowest that remain, and those
7 will be the ones that will be invited in for voir dire on the
8 14th.

9 I think we need to let you know exactly who they are
13:24:54 10 so you can review their questionnaires and be prepared to ask
11 them.

12 Traci, is there an easy way to do that?

13 (The Court and the courtroom deputy confer.)

14 THE COURT: We'll have Traci and Nancy come up with
13:25:14 15 that list and send it to you. If you disagree with it based
16 on who we've excused for hardship and cause, give us a call so
17 we can get it right. But we'll try to get that done early
18 next week so you have time to look over the questionnaires of
19 the jurors who will be called in.

13:25:31 20 MR. WENNER: Your Honor, I just -- do you have a
21 preference -- and maybe you already said this and I
22 apologize -- do you have a preference on the way jurors are
23 struck for peremptories? Is it simultaneous? Is it --

24 THE COURT: Our local rules, it's simultaneous and
13:25:43 25 secret. Each side three strikes.

13:25:50 1 All right. Any other questions on the jury
2 selection?

3 Okay. Thanks for coming down.

4 MR. WENNER: Thank you, Your Honor. Sorry again
13:26:01 5 about the dress.

6 THE COURT: That's all right.

7 (Mr. Wenner exited the courtroom.)

8 THE COURT: Let's talk about the other issues that I
9 mentioned before we broke.

13:26:21 10 One of those was the direction of migration. And I
11 think the argument, if I remember from the plaintiffs -- I'm
12 sorry, from the defendants was that since Ms. Booker's filter
13 migrated away from the heart, there shouldn't be any evidence
14 of prior instances of migration toward the heart; is that
15 right?

16 MR. NORTH: Yes, Your Honor. That's correct.

17 THE COURT: Okay. Let me hear plaintiffs' reasons
18 for why you think it's relevant, and then I'll hear from
19 defense counsel.

13:27:03 20 Before we do that, though, I just want to read again
21 briefly the order so I refresh my memory as to exactly what I
22 was thinking before.

23 Okay. Mr. Lopez.

24 MR. LOPEZ: Thank you, Your Honor.

13:28:14 25 As the Court knows, the G2 is the -- I think

13:28:19 1 Mr. Carr describes it as the successor of the Recovery
2 filter. The reason the G2 exists is because of the design
3 and the clinical performance of the Recovery filter. So
4 from -- from a regulatory history part of this case, it is
13:28:40 5 hard to parse out, you know, one major complication in
6 particular. It's the complication that is the reason the G2
7 exists.

8 So the jury needs to hear what it was about the
9 Recovery that formed the state of mind of Bard when it went
13:28:57 10 on to design the G2. As a matter of fact, Mr. Carr and
11 others testify it was the knowledge from that clinical
12 experience that they were -- that they applied in designing
13 the G2.

14 It's plaintiffs' position in this case they didn't
13:29:13 15 do a very good job of taking that into consideration. They
16 did not consider the fact that this device had more than not
17 just caudal migration -- I'm sorry, cephalad migration. It,
18 in fact, suffered from migration in both directions. In
19 fact, the very first migration that existed in -- with the
13:29:30 20 Recovery filter was in the Asch pilot study, and the one
21 patient in that study, in fact it was number 9, first patient
22 got challenged by a clot that the device actually went down
23 first, and then it went up.

24 So the issue is really the stability of the device
13:29:45 25 and how do you keep it where it's supposed to be and where

13:29:48 1 you put it. And I'll point out to you this: That in -- I
2 think when you addressed this in your order on the motion,
3 you asked for instances and why it's relevant. Well, when
4 Bard was doing their analysis of migration and representing
13:30:05 5 this to FDA and others, they didn't parse out whether or not
6 it was cephalad migration or caudal migration. As a matter
7 of fact, they grouped them together because by doing so and
8 just calling this migration, like they do -- their IFU just
9 says migration, it doesn't say in what direction. By
13:30:25 10 combining these two, and we have an HHE dated February of
11 2006 where, within that document, they actually describe that
12 they have ten migrations, and therefore they fare well with
13 the SRI guidelines and the percentages as its migration.

14 Our position is they shouldn't have done that. They
13:30:44 15 should have compared the number of caudal migrations to the
16 number of caudal migrations with other devices. So when it's
17 convenient for them to put them together for purposes of
18 showing that their complication rate of migration is not so
19 bad, they do it. And now they want to come here and say we
13:31:01 20 should take out cephalad migrations as an issue, a relevant
21 issue, in Ms. Booker's case.

22 The other thing I -- maybe this is maybe even more
23 important than that, Dr. Kessler, our regulatory expert, is
24 going to testify that the Recovery filter was obviously not
13:31:23 25 an appropriate predicate for the G2, that because of its

13:31:28 1 complications, primarily the complication of death and
 2 cephalad migrations, the device should have been taken off
 3 the market and not used as a predicate for the G2. In other
 4 words, it was adulterated. It was adulterated not just
 13:31:43 5 because of one complication, but because of the totality of
 6 the problems with the Recovery filter.

7 It wasn't until there were, I think the fourth or
 8 fifth death of the Recovery device, I think I have the
 9 company's timeline on that, that they actually decided to --
 13:32:03 10 it's time for us to redesign this and it's time for us to
 11 come out with a second generation of the Recovery.

12 So those events that led to the development of the
 13 G2 primarily and, in fact, if -- when you look at the -- it
 14 fractured, too, but the primary problem with the Recovery
 13:32:21 15 filter was cephalad migrations, and then all of the testing
 16 and all of the decisions that the company made as a result of
 17 that become relevant in this case.

18 It's going to be plaintiffs' position they didn't
 19 take that very seriously when they -- in view of all of those
 13:32:36 20 problems, including deaths from this device moving in both
 21 directions; they should have really done a lot more than they
 22 did.

23 Again, the IFU does not distinguish cephalad
 24 migration from caudal migration. Now, I'll also tell you
 13:32:53 25 this: That in the one pilot study they did, it's called the

13:32:56 1 Everest study, we talked about this morning -- I guess I
2 should have turned on the Elmo. You can probably see that
3 from here. I don't know if you see it, Judge --

4 THE COURTROOM DEPUTY: You can --

13:33:11 5 MR. LOPEZ: Can I use the Elmo?

6 THE COURTROOM DEPUTY: Yeah. It's on. Give it a
7 second to turn on.

8 Here, I'll come around.

9 I apologize. I don't know why it's not coming up.

13:34:34 10 I'll work on that.

11 THE COURT: Why don't you just hold it up.

12 MR. LOPEZ: I think you can probably see it, Judge,
13 if I can just approach a little closer.

14 THE COURT: That's fine.

13:34:41 15 MR. LOPEZ: So this line here is where the device is
16 supposed to stay if you put it in. Everything below the line
17 is caudal migration. And this is in their clinical study.
18 And everything above the line is cephalad migration. The G2
19 filter had 21 migrations cephalad and 60 caudal. It
13:35:04 20 definitely had a worse caudal history, but --

21 THE COURT: Show defense counsel what chart you're
22 showing me.

23 Okay. Go ahead, Mr. Lopez.

24 MR. LOPEZ: And, again, in the IFU of the G2, they
13:35:36 25 don't distinguish between the difference in migrations. The

13:35:40 1 brochure that Bard used for the G2 filter that Ms. Booker
 2 received represents the G2 filter as combining the best design
 3 features of Bard's existing --

4 THE COURT: Could you speak at the mic, please.

13:35:55 5 MR. LOPEZ: I'm sorry. The G2 filter combines the
 6 best design features of Bard's existing vena cava filters to
 7 create a brand-new permanent filter platform taking strength
 8 and stability to a new level. Meaning they made -- they
 9 created a device that would not migrate. It didn't say
 13:36:13 10 whether it was better going up or down, it was a device more
 11 stable, would stay where you put it.

12 Dr. Kessler, in his report, will render the
 13 following opinion: That if Bard had removed the Recovery
 14 filter from the market in April or May 2004, as I believe it
 13:36:35 15 should have, there would have been no legally marketed
 16 predicate for Bard to have claimed substantial equivalence
 17 for a new device. Thus, the G2 filter that had the Recovery
 18 filter as its predicate could not have been legally marketed.
 19 That is based on a statistically significant analysis done by
 13:36:56 20 Natalie Wong -- you've heard about that before -- where she
 21 compared the fatalities from cephalad migration of the
 22 Recovery filter to its predicate and some competitors -- and
 23 its competitors, but more importantly to the Simon Nitinol
 24 filter, and determined that it had statistically
 13:37:13 25 significantly higher incidents of migrations causing death.

13:37:19 1 And that is in support of what Dr. Kessler says
2 about the fact that that is the reason the Recovery, among
3 other reasons, but that certainly is among his opinions as to
4 why the Recovery was an inappropriate predicate.

13:37:34 5 And then Dr. Kessler further states -- let's see.

6 57. In Bard's March 2, 2005, special 510(k) modification to
7 the Recovery filter, which was subsequently replaced with a
8 traditional 510(k), Bard stated that the modified Recovery
9 passed the filter migration resistance test. Bard included
13:38:01 10 the following footnote: The predetermined acceptance
11 criteria for this test was inappropriately established to be
12 statistically significant or equivalent to Bard's
13 Simon Nitinol filter. The more appropriate acceptance
14 criteria should have been defined to demonstrate equivalence
15 to or improvement over the predicate device current Recovery
16 filter.

17 What happened in this case, Your Honor, they
18 acknowledged that when they were first testing this device,
19 the G2, that because of the problems they had with the
13:38:30 20 Recovery filter, that they should be comparing themselves to
21 the Simon Nitinol filter for purposes of migration,
22 performance, and whether or not it was as safe and effective
23 as the Simon Nitinol filter. Bard did that. Bard did that,
24 but they never shared that information with FDA. They failed
13:38:48 25 those tests.

13:38:52 1 So what they did in order to be able to represent to
2 the FDA that they are substantially equivalent, they tested it
3 against the Recovery filter and lowered the threshold for
4 migration to a level that their own experts were saying was
13:39:05 5 too low against migration resistance. And it was migration
6 resistance cephalad, towards the heart. They never tested it
7 going in the opposite direction until the device was on the
8 market for about a year and a half.

9 So they used the Recovery -- this is one of the
13:39:22 10 instances where we're saying the Recovery filter should not
11 have been used as a predicate device for the Simon Nitinol
12 filter -- I mean for the Recovery filter -- I'm sorry. Let me
13 start over. That the Recovery filter should not have been
14 used as a predicate device for the G2, and our regulatory
13:39:41 15 expert is going to say that, and that they inappropriately
16 changed that threshold and -- to the -- from the Simon Nitinol
17 to the Recovery.

18 Again, Bard's entire knowledge -- you can't really --
19 you can't parse out these things. You can't talk about the
13:40:03 20 Recovery and not bring in the most important reason why it was
21 an inappropriate device to be used as a predicate device and
22 why this company should have taken it off the market. If
23 we're going to talk about the transition and the iteration
24 and -- from Recovery, they're going to say that's just a
13:40:20 25 normal thing, you go in and you make a device -- you keep

13:40:23 1 improving your device based on its, quote, clinical
2 performance. That's their testimony.

3 Now, when we deal with that in evidence in this
4 trial, we should be able to talk about its entire clinical
13:40:35 5 performance, not just one or two.

6 THE COURT: Okay. I understand that point.

7 Thank you.

8 MR. LOPEZ: Thank you, Your Honor.

9 THE COURT: Defense counsel.

13:40:49 10 MR. LOPEZ: And, Your Honor, one other thing on the
11 timeline. They didn't start redesigning the G2 until they had
12 their fifth death from a cephalad migration.

13 I'm going to put the penny back.

14 THE COURT: It's working now, so put the penny back.

13:41:20 15 MR. NORTH: Thank you, Your Honor. In our view, this
16 is actually one of the most important evidentiary questions in
17 the case. More important than whether the Recovery filter in
18 general is admissible. It -- this issue of cephalad
19 migration.

13:41:31 20 The plaintiffs want to get in front of this jury and
21 inflame this jury with evidence of 19 reports of death from
22 the cephalad migration of the Recovery filter. Cephalad
23 migration is a very, very unique complication with these
24 filters. It has been reported in the literature back to the
13:41:53 25 1990s. With all different models.

13:41:56 1 Cephalad migration, as the Court knows, is an upward
2 movement. But what happens in these severe cases is the
3 entire filter becomes dislodged, usually because of a very
4 massive clot burden, but it becomes unanchored, dislodged,
13:42:12 5 and the whole clot travels to the heart, often, although not
6 always, resulting in death. Again, it has been reported that
7 all filters, but there were 19 reports of it leading to death
8 with the Recovery filter. The majority of those reports of
9 cephalad migration with the Recovery filter were in morbidly
13:42:30 10 obese patients.

11 That has -- that failure mode, that complication,
12 has absolutely no relevance, in our view, to what transpired
13 with Ms. Booker.

14 If Ms. Booker's filter migrated at all, and there's
13:42:48 15 some debate in the evidence as to that. It's uncontroverted
16 that it migrated caudally, downward, a very small amount.

17 That was a phenomenon that developed with G2 filter
18 in some instances, and the Court will hear a lot of testimony
19 about this during the trial in the investigations that Bard
13:43:11 20 did about caudal migration.

21 In the effort to make the G2 more migration
22 resistant to prevent cephalad migration, the engineers at
23 Bard succeeded. To our knowledge, there has not been a
24 single report of cephalad migration of a G2 filter leading to
13:43:30 25 death. Not a single report, with over 130,000 sold.

13:43:35 1 For that matter, with regard to the G2 filter, and
 2 looking at the failure mode that occurred with Ms. Booker,
 3 which is where one strut breaks off and goes to the heart and
 4 becomes embedded in the heart, to our knowledge, Bard has not
 13:43:51 5 a single reported incident of a G2 strut traveling to the
 6 heart and resulting in a death. Out of 130,000-plus sold.

7 We believe that evidence shows that this -- those
 8 factors show that cephalad migration simply is not relevant
 9 to Ms. Booker's case.

13:44:17 10 The redesign of the G2 to prevent cephalad migration
 11 worked. It was much more stable. If it went anywhere, it
 12 went down a little, and most doctors agree -- although the
 13 plaintiffs will dispute this at trial, I acknowledge that --
 14 most doctors will agree that caudal migration is a far
 13:44:37 15 different beast than cephalad migration. Caudal migration
 16 doesn't result in death. Caudal migration is not a
 17 catastrophic event in most -- in virtually all cases. Caudal
 18 migration is most often asymptomatic.

19 Now, the plaintiffs' experts will try to argue,
 13:44:54 20 Well, it leads to tilt or perforation or other things. But
 21 nobody suggests that caudal migration is sort of the drastic
 22 event leading to potential death like cephalad migration, and
 23 they won't be able to come in and put a single report that
 24 would suggest that.

13:45:12 25 The plaintiffs' attempt to overcome what we believe

13:45:15 1 is a lack of relevance by just sort of mixing all together
2 all migrations, well, all migrations are not the same. Yes,
3 when we report to the FDA, there's only one code we can use
4 for migration. But internally, when we trend, when Bard
13:45:34 5 trends reports of migration, it separates between caudal and
6 cephalad, because caudal and cephalad have different risk
7 factors. Caudal and cephalad migration have different
8 severities. Cephalad migration can lead to death. Caudal is
9 not associated with that.

13:45:54 10 We believe that this evidence, because of that, is
11 simply not relevant to whether the G2 was defective, because
12 this G2 did not migrate in a cephalad fashion in Ms. Booker,
13 and in general the G2 does not migrate, at least to a
14 catastrophic level, in the cephalad direction.

13:46:15 15 Interestingly, the chart from Everest that Mr. Lopez
16 showed you, it had a few little blips for cephalad migration
17 from the Everest study above, but they were all within the
18 20-centimeter range.

13:46:31 19 And the medical literature and FDA recognizes that
20 you don't truly call something a migration until it migrates
21 a certain length. And those were all in the green area on
22 that chart, showing they did not migrate to the extent they
23 would be classified as a migration.

24 25 And why is that reported there? We've tried to show
at science day, I think both sides did, the IVC is a very

13:46:54 1 dynamic thing, piece of the anatomy. And when you put that
 2 filter in, it is not be going to be absolutely static. And
 3 that's why the experts recognize that there can be some
 4 slight movement up or down, and then they'll call that a true
 13:47:07 5 migration. And there wasn't a single true migration found in
 6 the Everest study, according to that chart.

7 For all those reasons, Your Honor, we believe that
 8 this evidence simply has no relevance to Ms. Booker's claim.
 9 Hers didn't migrate that direction, because she didn't die,
 13:47:25 10 because the G2 doesn't migrate that direction, and because
 11 the G2 doesn't lead to cephalad migration deaths.

12 But even if that evidence were -- had a minimally
 13 probative value, and we certainly don't believe it does in
 14 this case, we believe this is an archetype 403 situation.
 13:47:46 15 Ms. Booker did not die. She did not have a cephalad
 16 migration. The G2 doesn't produce those.

17 Why should the plaintiffs be able to come in and
 18 inflame this jury with reports of 19 deaths in a predecessor
 19 filter that has since been redesigned into the G2, redesigned
 13:48:07 20 in part to address this very problem, and which addressed
 21 this problem successfully?

22 Why should they be able to inflame this jury if this
 23 evidence has any probative value? They want to talk at
 24 length, as we look at their deposition designations, about
 13:48:24 25 what we did to investigate the death, what we did to talk

13:48:29 1 about publicity, what we did about the deaths, over and over.
2 With one witness, they questioned like for 20 minutes how
3 many deaths was enough, how many deaths was enough, how many
4 deaths was enough.

13:48:41 5 They're trying to inflame this jury, and we think
6 this is classic Rule 403 exclusion, even if it ever got over
7 the 401 or 402 hurdle.

13:48:59 8 This Court has ruled they may get other Recovery
9 filter evidence in, and there's Recovery filter evidence
regarding fracture of that predicate device. And the Court
10 has ruled that's relevant. Well, fracture does have
11 relevance as a complication mode to Ms. Booker's case. But
12 cephalad migration does not.
13

14 And for those reasons, Your Honor, we would ask that
15 the Court exclude that evidence.

16 THE COURT: All right. Thank you.

17 Mr. Lopez, what is your response to Mr. North's
18 assertion that the G2 largely resolved the cephalad migration
19 problem, that there were no deaths based on cephalad
migration, that the migration in that direction in the study
20 you showed was all within 20 centimeters?

22 MR. LOPEZ: I'm glad you asked.

23 That study was restricted to a maximum follow-up of
24 180 days. I mean, every significant migration begins
somewhere. And the fact that this device was not stable in
25

13:50:40 1 either direction after the design history they had with the
2 Recovery filter, they had evidence of that in a very
3 short-term study. That study was not designed to find that.
4 The longer term study --

13:50:53 5 THE COURT: Let me make sure I understand. It sounds
6 like you're agreeing that none of those migrations was more
7 than 20 centimeters. You're just saying it was just too short
8 of a study.

13:51:04 9 MR. LOPEZ: No -- well, yeah, it was too short of a
10 study and the FDA standard in their guidance document is five
11 millimeters. Many of those were more than five millimeters in
12 a cephalad direction.

13:51:20 13 THE COURT: What -- besides that study, what is the
14 evidence you would present to show that the G2 has a cephalad
15 migration problem?

16 MR. LOPEZ: There are complaints -- I mean, I don't
17 have them with me, but there are complaints about migrations
18 in both directions.

19 THE COURT: What, MAUDE database complaints?

13:51:35 20 MR. LOPEZ: I don't know if you call them MAUDE or
21 whether or not it's their own complaint files in TrackWise.

22 THE COURT: These would be the Bard internally
23 tracked complaints.

24 MR. LOPEZ: Right.

13:51:42 25 You know, I think the issue isn't relevance. I

13:51:44 1 mean, shouldn't a jury decide whether or not Bard should have
2 taken into consideration that history with the Recovery
3 filter in designing the G2? Did they do that?

4 THE COURT: Here's what I'm wrestling with: If we
13:52:01 5 take a hypothetical of an automobile case where the plaintiff
6 is claiming that the automobile is negligently designed
7 because the suspension was faulty and it led to a rollover at
8 an intersection --

9 MR. LOPEZ: Right.

13:52:12 10 THE COURT: -- should the plaintiff in that case be
11 able to present evidence that the predecessor version of that
12 automobile had a brake problem, when there is no evidence in
13 the plaintiff's case that it had anything to do with the
14 brakes, it's all focused on the suspension? Should the
13:52:32 15 plaintiff be able to say, Well, this predicate was defective
16 in brakes as well, when it had no connection to the
17 plaintiff's injury?

18 MR. LOPEZ: Yeah, I'm not sure that's a good
19 hypothetical, because you've now separated out two parts of
13:52:42 20 the automobile. Now, if you have -- if the original
21 automobile had a suspension problem that caused accidents, and
22 you knew that your problem was suspension, then you redesigned
23 it and you created a new problem by overdesigning it or not
24 taking into consideration fixing the first one was going to
13:53:04 25 cause a new problem, yes, it's relevant.

13:53:06 1 But you're right, if this was a brakes versus
 2 suspension. But this is the same problem; it was a stability
 3 problem.

13:53:16 4 When they designed the G2, they had in mind, We've
 5 got to fix this serious problem we had with cephalad
 6 migration, and in doing so, they -- first of all, they
 7 didn't -- they fixed it a little bit, it still moves up and
 8 down, but they created a whole new serious problem.

9 And despite what Mr. North said --

13:53:34 10 THE COURT: Let me stop you right there. You said
 11 that a couple times, "they created a new problem." Are you
 12 going to have experts who will say that the fixes Bard put in
 13 place to stop cephalad migration created caudal migration?

14 MR. LOPEZ: Our first expert, Dr. McMeeking.

13:53:56 15 The unfairness of this, Judge, they don't separate
 16 migration in any of the discussions they have until now, for
 17 the courtroom. In their IFU, in their discussions with FDA,
 18 in doing the comparisons between their rates of migration,
 19 it's always about migration, whether it be cephalad or
 20 caudal.

13:54:14 21 And now they want to come in, and for the first
 22 time, you know, make you, and I guess the jury, believe that
 23 those two instances are not related. They're clearly
 24 related. They have to do with the way these devices are
 25 designed.

13:54:30 1 Plus more importantly, Your Honor, shouldn't we have
2 an opportunity to tell the jury that the G2 shouldn't be on
3 the market because the former head of the FDA, who is our
4 expert, says that it should not -- it was an inappropriate
13:54:45 5 predicate device for that purpose because of its
6 statistically significant instances of fatalities with
7 cephalad migration and pieces of this thing going upward, and
8 not downward.

9 Let me say this, Judge, I know you're thinking --

13:55:13 10 THE COURT: Hold on a minute. I'm thinking about the
11 last point that you just made.

12 Here's what I'm wrestling with on that point, and
13 you made it during your first argument as well: You seem to
14 be saying that part of your argument to the jury should be
13:55:51 15 that the Recovery had this cephalad migration problem, it
16 caused 19 deaths; if Bard had dealt with that responsibly,
17 they would have pulled it off the market, there would have
18 been no predicate device, therefore the G2 never would have
19 come upon the market and never would have injured
13:56:09 20 Mrs. Booker.

21 MR. LOPEZ: That's one of arguments, yes.

22 THE COURT: That seems to me to be an argument that
23 because Bard -- I'm having trouble seeing how that is a
24 defective design or a failure to warn claim. It seems to be
13:56:23 25 arguing Bard was negligent in failing to take the Recovery off

13:56:28 1 the market and the "but for" cause that resulted was the G2
 2 came onto the market and hurt our client.

3 You don't have a general negligence claim in the
 4 case or a claim of negligent failure to recall the Recovery
 13:56:44 5 claim.

6 MR. LOPEZ: We do have a negligence design cause of
 7 action.

8 THE COURT: Right. But I'm having trouble with the
 9 argument that because the Recovery was defective and should
 13:56:54 10 have come off the market, and therefore there would have been
 11 no predicate, but that somehow proves negligent design of the
 12 G2. I'm having a hard time squaring your argument --

13 MR. LOPEZ: Well, here's where bringing the 510(k)
 14 process into the case comp- -- it makes that relevant all of a
 13:57:15 15 sudden because in order for them to get clearance of a device,
 16 it has to be substantially equivalent to a predicate device;
 17 otherwise there is no G2.

18 So the fact that we now have the 510(k) clearance
 19 process in this case, the plaintiffs have to have an
 13:57:31 20 opportunity to put on testimony, expert testimony, that
 21 describes why they violated that process. And one of the
 22 reasons -- the ways they violated that process was by not
 23 using a legally marketed device. They used the wrong
 24 predicate. They started to use the right predicate, and then
 13:57:51 25 went back to the Recovery filter.

13:57:53 1 I mean, how do we defend that case? I mean, I'm
 2 sorry, how do we deal with that evidence that this thing was
 3 cleared by FDA without being able to show evidence that the
 4 only reason it got cleared by FDA is because Bard used an
 13:58:08 5 inappropriate device?

6 And the other thing, we don't have time to inflame
 7 this jury going through each one of these 19 deaths. We
 8 understand that. But the jury should at least know the
 9 history of the -- the regulatory history of the Recovery
 13:58:26 10 filter and why we have a G2. Number one.

11 Number two is: Why is the G2 really not better? In
 12 many instances, it was worse than the Recovery filter. It --
 13 maybe it didn't migrate in a cephalad direction, but it had
 14 worse migration issues. And Bard did not change their IFU to
 13:58:47 15 say, you know, caudal migration, cephalad migration. They
 16 group it as migration. This is an issue about whether or not
 17 migration is relevant and the tests that they put this thing
 18 through, and their frame of mind as they were designing and
 19 testing the new G2.

13:59:05 20 THE COURT: Okay. I understand the positions.

21 I want to think about this issue. So in the order
 22 that comes out early next week, I'll give you a ruling on
 23 this issue.

24 All right. Let me mention a couple of other issues.
 13:59:21 25 They're not really issues. Things I wanted to bring up

13:59:24 1 today.

2 Is the rule of exclusion going to be invoked in the
3 case?

4 MR. NORTH: I'm sorry, what?

13:59:30 5 MR. CONDO: The rule of exclusion.

6 Your Honor, we would invoke the rule, but invoke
7 that section of 615 that allows us to share the expert
8 testimony with our experts. We think that in -- particularly
9 in a time-constrained trial, it's more efficient and
13:59:48 10 certainly helpful to the lawyers to allow the experts on both
11 sides to have access to the testimony.

12 THE COURT: And by access, you mean sit in at the
13 trial or just be able to hear from the lawyers what was said?

14 MR. CONDO: Hear from the lawyers or receive the
14:00:03 15 transcripts.

16 THE COURT: Okay.

17 MR. CONDO: It's the functional equivalent of being
18 in the courtroom when they're not going to be here.

19 THE COURT: Any objection to that from the plaintiff
14:00:10 20 side?

21 MR. O'CONNOR: No, we would object to that,
22 Your Honor. We want --

23 THE COURT: So you're saying you can't tell your
24 experts anything about what the defense experts say before
14:00:27 25 they testify?

14:00:31 1 MR. LOPEZ: Problem is ours go first.

2 THE COURT: Well, you may have rebuttal experts.

3 You're saying the experts -- well, you can't tell one of your
4 experts what your other expert said at trial? Is that really
14:00:41 5 the position you want to take?

6 MR. O'CONNOR: Well, I didn't understand that's what
7 Mr. Condo was saying. Maybe I misunderstood.

8 THE COURT: Well, I asked -- the question I asked is,
9 is the rule being invoked. And the defendant said yes, it's
14:00:53 10 invoking it, but each side ought to be able to tell their
11 experts what other experts have said during the trial so that
12 they can testify.

13 MR. O'CONNOR: Then we would agree with that. I
14 misunderstood.

14:01:06 15 THE COURT: All right. But what that means is I'm
16 leaving it to all of you to advise your witnesses about --
17 your nonexpert witnesses about the rule, tell them they need
18 to not take steps to learn about what is said during trial,
19 and to stay out of the courtroom.

14:01:19 20 MR. O'CONNOR: Well, Your Honor, what I would like,
21 though, is a clarification. When the experts are going to
22 have access to what was said here in court, does that mean
23 they're going to be handed transcripts of the testimony?

24 THE COURT: Well, we just talked about that. And
14:01:31 25 Mr. Condo said either told by the lawyers or shown

14:01:34 1 transcripts.

2 I mean, it seems to me that all of you are going to
3 want your experts to know what the other experts have said.
4 In fact, there's lots of case law that says experts can sit
14:01:47 5 in at trial notwithstanding invocation of the rule because
6 they're responding to what other experts say.

7 MR. O'CONNOR: I understand now.

8 THE COURT: Okay. So the rule's invoked with the
9 caveat that you can talk to experts about what was said during
14:02:00 10 their testimony -- during other experts' testimony, or you can
11 show them the transcript.

12 But I'm not going to advise the witnesses of the
13 rule at the beginning of the day like some judges do. I'll
14 leave it up to you.

14:02:16 15 I want to remind you -- I know you know this, but
16 this rule is often disregarded. I want to remind you that
17 opening statements are not arguments. And I am a believer in
18 that rule. And I really don't want to interrupt either side
19 during your opening. So please keep it to a statement of
14:02:37 20 what you believe the evidence will show. If you start
21 lapsing into argument, I'm likely to interrupt you even if
22 there's not an objection and remind you just to preview the
23 evidence.

24 With respect to jury instructions, we are going to
14:02:52 25 try to get a draft of the final jury instructions done next

14:02:58 1 week so you can see them before we start trial. I'm not
2 certain we'll get that done, but we're going to try.

3 Oh, by the way, one of the other things that we will
4 do next week is get you a ruling on the summary judgment in
14:03:09 5 the *Jones* case so you'll get that. You talked about wanting
6 to get that before trial.

7 We're also going to try to get you the jury
8 instructions, and then what we'll do is find a time in that
9 first week of trial or the second week to talk about your
14:03:23 10 reaction to my proposed jury instructions. But we'll try to
11 get you my draft sometime next week. Based, obviously, on
12 what you all have submitted.

13 Looks like you have a question, Mr. O'Connor.

14 MR. O'CONNOR: Well, you brought up the *Jones* case,
15 and that was right on the -- right behind this one, and I'm
16 just thinking ahead. If we're going to use juror
17 questionnaires on that, when should those be submitted? I
18 think we've kind of penciled in the time based on what
19 happened here in our office.

14:03:53 20 THE COURT: I haven't even looked at that. We'll
21 look at that and figure it out.

22 MR. O'CONNOR: All right.

23 THE COURT: Okay. Let me see if there's anything
24 else.

14:04:13 25 Oh, yeah. You were going to look at the voir dire

14:04:16 1 and the preliminary instructions that were handed out this
2 morning. Do you have any comments on those?

3 MR. NORTH: None from the defendant, Your Honor.

4 MR. LOPEZ: None here, Your Honor.

14:04:31 5 THE COURT: Okay.

6 All right. Plaintiffs' counsel, do you have other
7 matters you want to raise today?

8 MR. LOPEZ: The only thing I -- well, we were talking
9 about it, I know you've taken this under submission, but in
14:04:52 10 the brief time we had, we counted 11 cephalad migrations, in
11 other words, upwards by the G2.

12 THE COURT: In --

13 MR. LOPEZ: In the first two years --

14 THE COURT: In complaint -- these are Bard internal
14:05:02 15 complaints?

16 MR. LOPEZ: Yes.

17 THE COURT: Okay.

18 MS. REED ZAIC: Your Honor, I'm the one that did the
19 quick count here. I'm sure there's more, that was just as
14:05:11 20 many as I could scribble at the moment.

21 THE COURT: Okay.

22 MR. LOPEZ: There's -- in the 11 -- in the 5,000
23 exhibit list, there's like 1100 -- there's -- we were able to
24 find 11 so far.

14:05:21 25 THE COURT: Mr. North.

14:05:23 1 MR. NORTH: Your Honor, just so the record is
2 straight, I want to make sure that nobody thought I was
3 misrepresenting things. There have certainly been reports of
4 cephalad migration on a number of instances, although not many
14:05:32 5 with a G2, but there's no reported death was my point.

6 THE COURT: That's what I understood you to be
7 saying.

8 All right.

9 MR. NORTH: Your Honor, I have just one question, and
14:05:39 10 I would like to bring a couple of witness availability issues
11 to the Court's attention.

12 My only question is during opening statements, does
13 the Court allow PowerPoint presentations?

14 THE COURT: Yes, I do, but I want you to exchange
14:05:51 15 them at least 48 hours ahead of time --

16 MR. NORTH: Okay.

17 THE COURT: -- so that if there are objections to
18 them, we can talk about those on the first morning of trial.

19 MR. NORTH: Okay. That's fine, Your Honor.

14:06:01 20 THE COURT: By the way, on that point, I'm going to
21 ask all of you to be here in the courtroom ready to go at 8:30
22 on March 14th. I'll come in at that time to see what
23 last-minute issues we need to address. The jury will be up
24 here probably shortly after 9:00 to start jury selection. So
14:06:17 25 we'll have a little time that morning. And if there's been an

14:06:20 1 issue on somebody's proposed PowerPoint, I'm happy to address
2 it then.

3 MR. NORTH: Okay. Your Honor, we have two issues
4 with witnesses I wanted to bring to the Court's attention. I
14:06:29 5 have raised both of these with the plaintiff, but have not
6 gotten a response from them as of this date.

7 They have subpoenaed 20 Bard, either present or
8 former, employees. One of those is a woman by the name
9 Natalie Wong, who is still employed by the company. Ms. Wong
14:06:46 10 is fighting a major debilitating medical condition. She just
11 returned to work recently after three months on medical
12 leave, found herself back in the hospital again this weekend.
13 She has uncontrolled blood pressure and migraine headache
14 problems that are apparently very debilitating. She now has
14:07:07 15 a doctor's excuse that says she cannot withstand the stress.

16 We would like to have her on the stand ourselves,
17 but she's just in no condition.

18 I don't know if they're going to object. They
19 haven't responded.

14:07:18 20 MR. LOPEZ: We just found out -- I mean, he's been
21 keeping us apprised, but we just found out this morning about
22 the nature and extent. So we cut her deposition
23 specifically --

24 THE COURT: So you're --

14:07:29 25 MR. LOPEZ: -- based on the fact that she may not be

14:07:31 1 able -- we're not going to make her come into this courtroom.

2 MR. NORTH: I just want to make sure I didn't need to
3 bring some doctor's thing --

4 MR. LOPEZ: I don't want you to think we're sitting
14:07:39 5 here being callous and not taking that into consideration.

6 THE COURT: I didn't think that, Mr. Lopez.

7 MR. NORTH: The other problem is a little more
8 unique. It is a former vice president of research and
9 development here at Bard Peripheral by the name of Abtihal
14:07:51 10 Raji-Kubba, and I'll give you the spelling later, Raji-Kubba.

11 Ms. Raji-Kubba has now moved on to become the president of a
12 related division of Bard called Lutonix, located in
13 Minneapolis. She is -- still maintains her residence in
14 Phoenix, because this new position happened a year or two ago
14:08:12 15 and she has children here, or grown children, I believe.

16 Her -- somebody served a subpoena at her residence a
17 couple of weeks ago, I believe it was served on her son. Be
18 that as it may, she is -- as president of the company, she is
19 scheduled to be either in Minneapolis or in other places on
14:08:34 20 business trips every single workday of the three-week trial.
21 We've asked them to consider using her deposition.

22 THE COURT: Hold on just a minute.

23 Mr. Lopez?

24 MR. LOPEZ: Your Honor, this is the first time at
14:08:47 25 least I'm knowing about this. If she's not available, if

14:08:49 1 she's under subpoena, and that seems like a pretty good reason
2 for us -- if we're even going to offer her testimony, use her
3 deposition.

4 MR. NORTH: Okay. I had asked them about this about
14:08:59 5 a week ago. I just wanted to be sure it was on the record.

6 THE COURT: Okay. That's fine.

7 Did you have other issues that you wanted to raise?

8 MR. NORTH: That's it, Your Honor.

9 MS. REED ZAIC: Culled exhibit list. Exhibit list.

14:09:11 10 Your Honor, there's an issue with -- I think you
11 understand the length of our exhibit lists. Defendants and
12 plaintiffs, in the past, have agreed on a method that may be
13 easier on courtroom staff and everyone involved. Obviously,
14 our master exhibits are extensive. But in the past we've
14:09:30 15 come to an agreement on what we call a culled exhibit list on
16 which we provide the copies so the courtroom isn't full of
17 all of the exhibits, and that's sort of a sense, after all of
18 this time we've been litigating this case, a sense of what we
19 are more likely to use than others. The master exhibit list
14:09:49 20 is usually provide just to make sure we're not caught in a
21 situation of nondisclosure.

22 We do have a better sense, I think, on each side of
23 what we would more likely use. And that culled exhibit list
24 allows for fewer boxes, fewer documents to be in the
14:10:02 25 courtroom.

14:10:03 1 The only issue that's been negotiated in the past,
2 and obviously the Court would have to agree to all of this,
3 but in the rare event that we would need to use something on
4 the master exhibit list, having that hard copy here so many
14:10:16 5 days in advance or hours in advance or whatever. We just met
6 and conferred about this outside, as we have in the past, and
7 defer to counsel if there's objections or further comment.

8 THE COURT: Any disagreement with that idea?

9 MR. NORTH: Your Honor, we defer to the Court's
14:10:30 10 preference. We're prepared to proceed either way.

11 THE COURT: Well, I think we should have fewer rather
12 than more documents in the courtroom. So I'm all for culling
13 down the exhibit list. And the stuff you think will be used,
14 we can have that here. That certainly will make it much
14:10:49 15 easier for Traci to pull exhibits for witnesses when they're
16 needed.

17 And if there's an exhibit that needs to be used that
18 isn't in a box in the courtroom, presumably you've got an
19 electronic copy, we could show it that way, or we could bring
14:11:01 20 it up later in the witness's testimony after a paper copy is
21 in. I'm all for reducing the amount of paper in the
22 courtroom.

23 MS. REED ZAIC: We can do that.

24 THE COURTROOM DEPUTY: That would be great.

14:11:14 25 THE COURT: All right. Anything else we need to

14:11:16 1 address?

2 MR. NORTH: Nothing from the defense standpoint,
3 Your Honor.

4 MR. LOPEZ: Nothing from the plaintiffs, Your Honor.

14:11:22 5 THE COURT: Okay. We will plan to see you at 8:30 on
6 Wednesday the 14th. My understanding is you are still
7 planning to get me trial briefs at the end of next week. If
8 you think those are needed. I mean, there's a fair amount of
9 material covered in the Final Pretrial Order.

14:11:40 10 You all still think those are needed?

11 MR. NORTH: We'll go back and revisit that and see,
12 Your Honor. I'm not absolutely certain.

13 THE COURT: What I don't need to have you do is sort
14 of review arguments that have been previously made in briefing
14:11:54 15 or in the Final Pretrial Order.

16 MR. NORTH: Okay.

17 THE COURT: If there's something new that you think
18 is going to be relevant to my decisions at trial, I'm happy to
19 get it. But there's -- I don't think there's a need to
20 synthesize, particularly since as we go through the jury
21 instructions, we're going to be taking a hard look at what the
22 right instruction is for the case as we understand it, and
23 that will become the focal point for any legal issues, I
24 think, that we need to address.

14:12:19 25 So it won't hurt my feelings if you decide to leave

14:12:23 1 out --

2 MR. NORTH: We'll certainly keep that in mind,
3 Your Honor. Trial memorandum.

4 THE COURT: Okay. We'll see you on the 14th. Thank
14:12:29 5 you.

6 (End of transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 12th day of March,
2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter